

January 17, 2019

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IN THE DISTRICT COURT OF CLEVELAND COUNTY  
STATE OF OKLAHOMA

STATE OF OKLAHOMA, ex rel.,  
MIKE HUNTER, ATTORNEY GENERAL  
OF OKLAHOMA,

Plaintiff,

No. CJ-2017-816

vs.

(1) PURDUE PHARMA, L.P.,  
(2) PURDUE PHARMA, INC.,  
(3) THE PURDUE FREDERICK COMPANY;  
(4) TEVA PHARMACEUTICALS USA, INC.;  
(5) CEPHALON, INC.;  
(6) JOHNSON & JOHNSON;  
(7) JANSSEN PHARMACEUTICALS , INC.;  
(8) ORTHO-McNEIL-JANSSEN  
PHARMACEUTICALS, INC. n/k/a  
JANSSEN PHARMACEUTICALS, INC.;  
(9) JANSSEN PHARMACEUTICA, INC.,  
n/k/a JANSSEN PHARMACEUTICALS, INC.;  
(10) ALLERGAN, PLC, f/k/a ACTAVIS, PLC,  
f/k/a ACTAVIS, INC., f/k/a WATSON  
PHARMACEUTICALS, INC.;  
(11) WATSON LABORATORIES, INC.;  
(12) ACTAVIS LLC; and  
(13) ACTAVIS PHARMA, INC.;  
f/k/a WATSON PHARMA, INC.;

Defendants.

Videotaped deposition of GARY VORSANGER, M.D.,  
Ph.D., taken pursuant to Notice, was held at the Law  
Offices of DRINKER BIDDLE & REATH, LLP, 105 College Road  
East, Princeton, New Jersey, commencing January 17,  
2019, 9:08 a.m., on the above date, before Amanda  
McCredo, a Court Reporter and Notary Public in the State  
of New Jersey.

January 17, 2019

2

## 1 A P P E A R A N C E S:

2 NIX, PATTERSON & ROACH, LLP  
3 3600 North Capital of Texas Highway  
4 Suite 350B  
5 Austin, Texas 78746

6 BY: TREY DUCK, ESQ.  
tduck@nixlaw.com  
7 (512)328-5333  
8 Attorneys for Plaintiff

9 LYNN PINKER COX & HURST, LLP  
2100 Ross Avenue, Suite 2700  
10 Dallas, Texas 75201  
BY: JERVONNE NEWSOME, ESQ.  
11 jnewsome@lynnllp.com,  
12 (214)292-3607  
13 Attorneys for Purdue Defendants

14 MORGAN, LEWIS & BOCKIUS, LLP  
1701 Market Street  
15 Philadelphia, Pennsylvania 19103  
BY: MARK A. FIORE, ESQ.  
16 mark.fiore@morganlewis.com  
17 (215)963-5000  
18 Attorneys for Teva, Watson, Cephalon, and Actavis  
19 defendants

20 O'MELVENY & MYERS, LLP  
400 South Hope Street  
18th Floor  
21 Los Angeles, California 90071-2899  
BY: CHARLES LIFLAND, ESQ.  
22 VINCENT S. WEISBAND, ESQ.  
clifland@omm.com  
23 vweisband@omm.com  
(213)430-6000  
24 Attorneys for Johnson & Johnson and Janssen defendants  
25 and the Witness

## 23 ALSO PRESENT:

24 James Soto - videographer

25 Maria Gomez - Nix, Patterson &amp; Roach, LLP

January 17, 2019

3

## I N D E X

## WITNESS

Gary Vorsanger, M.D., Ph.D.

## EXAMINATION BY

## PAGE

Mr. Duck

6, 303

Mr. Lifland

224

## RULING

## PAGE

## LINE

## QUESTIONING ATTORNEY

152

15

Mr. Duck

## EXHIBITS

## EXHIBIT

## PAGE

Vorsanger 1 JAN-MS-0214093 through 094

46

Vorsanger 2 JAN-MS-02149085 through 086

54

Vorsanger 3 JAN-MS-00641019 through 022 65, 301

Vorsanger 4 JAN-MS-02102600 through 602

73

Vorsanger 5 JAN-MS-02102624 through 626

73

Vorsanger 6 JAN-MS-00491920

115

Vorsanger 7 JAN-MS-00605509 through 510

122

Vorsanger 8 JAN-MS-00337085 through 086

138

Vorsanger 9 JAN-MS-02337833 through 835

140

Vorsanger 10 JAN-MS-02102667 through 671 155, 299

Vorsanger 11 JAN-MS-00314736 through 745

158

Vorsanger 12 JAN-MS-02258276

164

January 17, 2019

4

1	Vorsanger 13	JAN-MS-00066073 through 095	167
2	Vorsanger 14	JAN-MS-02132383 through 387	189
3	Vorsanger 15	Highlights of Prescribing Information	240
4	Vorsanger 16	JAN-MS-02321524	248
5	Vorsanger 17	JAN-MS-02305132	253
6	Vorsanger 18	JAN-MS-00151777	270
7	Vorsanger 19	JAN-MS-02754767	273
8	Vorsanger 20	Review Article	276
9	Vorsanger 21	Long-term opioid management for chronic noncancer pain (Review)	278
10	Vorsanger 22	Evaluation of the tamper-resistant properties of tapentadol extended-release tablets: Results of in vitro laboratory analyses	286
11	Vorsanger 23	JAN-MS-01489228 through 275	290
12	Vorsanger 24	JAN-MS-00228548	295
13			
14			
15			
16			
17			
18			
19			
20			
21			
22			
23			
24			
25			

January 17, 2019

5

1 THE VIDEOGRAPHER: Good morning. We're on  
2 the record. The time is 9:08 a.m. Today is  
3 the 17th day of January, 2019.

4 We're here at 105 College Road East,  
5 Princeton, New Jersey, for the purpose of  
6 taking the videotape deposition of Dr. Gary  
7 Vorsanger in the matter of the State of  
8 Oklahoma versus Purdue Pharma, LP, et al.

9 The videographer is James Soto, the court  
10 reporter is Amanda McCredo, both with U.S.  
11 Legal Support.

12 Counsel please identify yourselves for the  
13 record.

14 MR. DUCK: Trey Duck, from Nix, Patterson,  
15 and Maria Gomez, from Nix, Patterson, on behalf  
16 of the State of Oklahoma.

17 MR. LIFLAND: Charles Lifland, O'Melveny &  
18 Myers, for Johnson & Johnson and Janssen  
19 Pharmaceuticals.

20 MR. WEISBAND: Vincent Weisband, O'Melveny  
21 & Myers, for Johnson & Johnson and Janssen  
22 Pharmaceuticals.

23 MR. FIORE: Mark Fiore, Morgan, Lewis &  
24 Bockius, on behalf of the Teva defendants.

25 MS. NEWSOME: Jervonne Newsome, with Lynn

1       Pinker Cox & Hurst, on behalf of the Purdue  
2       defendants.

3               THE VIDEOGRAPHER: Thank you.

4               Please administer the oath.

5       GARY VORSANGER, the witness herein, after having been  
6               first duly sworn by a Notary Public of the  
7               State of New Jersey, was examined and  
8               testified as follows:

9                               \* \* \*

10              MR. LIFLAND: So, we -- before we went on  
11              the record, we discussed a stipulation  
12              regarding objections. And the stipulation is  
13              that, my objections will also apply for the  
14              other parties here, Purdue and Teva, but not  
15              vice versa. If they object and I want to  
16              object, I will make that objection on the  
17              record separately.

18              MR. DUCK: Great. Thank you.

19       EXAMINATION BY

20       MR. DUCK:

21              Q     Good morning, Dr. Vorsanger.

22              A     Good morning.

23              Q     How are you doing?

24              A     I'm doing okay, thanks.

25              Q     Can you please introduce yourself to the

1 jury?

2 A Sure. My name is Gary Vorsanger.

3 You want my background, Counsel?

4 Q That would be great. Please.

5 A Okay. By way of my training, I'm an M.D.,  
6 Ph.D. I received my Ph.D. before I went to medical  
7 school. I received my Ph.D. from the City  
8 University of New York and went to medical school at  
9 the Mount Sinai School of Medicine, also in New  
10 York.

11 After completing my medical training, I  
12 went on to do an internship and a residency at  
13 Montefiore Hospital & Medical Center in New York.  
14 That culminated in me getting a board certification  
15 in internal medicine.

16 After my training in internal medicine, I  
17 went up to Massachusetts, up in Boston, and I did a  
18 residency at the Massachusetts General Hospital in  
19 anesthesiology. I completed that residency, and  
20 then I was invited to come on as a staff  
21 anesthesiologist at the Massachusetts General  
22 Hospital. I was there for several years, and then I  
23 transitioned to a private practice in the anesthesia  
24 setting. I did that for several years, and then I  
25 went to the pharmaceutical industry.

Carly W. Sanger, M.D.  
January 17, 2019

8

1 My positions --

2 Would you -- do you want me to continue?

3 Q Please. Let's -- let me ask you a question  
4 to maybe slow things down a little bit.

5 A Sorry.

6 Q No, that's okay. You're, you're giving us  
7 a good background, which is great. You may speak a  
8 little quickly, and I'm just looking out for Amanda  
9 here.

10 A Right. I'm from New York, sorry.

11 Q No problem.

12 So, you mentioned that you went into the  
13 pharmaceutical industry.

14 I would like to hear about where you first  
15 started in the pharmaceutical industry.

16 A Sure. So, my first position in the  
17 pharmaceutical industry was at Astra USA -- that was  
18 before AstraZeneca -- and I was a medical advisor  
19 there.

20 Q And what were your responsibilities as a  
21 medical advisor at Astra?

22 A So, I provided expertise to the people at  
23 Astra. They were developing a local anesthetic, a  
24 medication, like Novocaine. And because of my  
25 background as an anesthesiologist, I was able to



1 provide -- and based on my real clinical  
2 experience -- on the types of questions that  
3 clinicians might have on how to use a medication  
4 safe and effectively. So, that was a good part of  
5 my role.

6 I also worked with their safety group for  
7 questions that may have come in from the field, as  
8 well.

9 Q Where was the first pharmaceutical industry  
10 job you had where you worked with opioid analgesics?

11 A So, I might have done a little bit of  
12 opioid analgesia work at Astra, because Astra at  
13 that time did market morphine. But most of the work  
14 that I did around opioid analgesia was the -- was  
15 when I was at Janssen.

16 Q When did you start working at Janssen?

17 A So, I started working at Janssen in October  
18 of 2000.

19 Q All right. And you currently work at  
20 Janssen, right?

21 A No. I actually retired from the company in  
22 June of 2017.

23 Q Congratulations.

24 A Thank you.

25 Q So, you worked at Janssen from 2000 until

1 2017?

2 A That's correct.

3 Q And did you hold various positions at  
4 Janssen during that time or the same position the  
5 whole time?

6 A So, there were different names of the  
7 companies, as -- from internal reorganizations. The  
8 work that I did was really in the work with the  
9 opioid analgesics. I started as a medical director.  
10 I was there for a period of -- I mean, I worked at  
11 that job for several years. And, again, the dates  
12 are approximate. And then I went on to become a  
13 senior medical director. And I held the position of  
14 senior medical director for quite a while, until I  
15 had retired.

16 At the -- yeah, just to answer your  
17 question. I had -- when I -- when the Nucynta --  
18 the U.S. rights for Nucynta were sold, I had other  
19 opportunities of things that I worked at at the  
20 company. I didn't do opioid analgesia afterwards,  
21 at that point, for the most part.

22 Q And that's because Janssen no longer had  
23 any opioid analgesics --

24 A That they were actively marketing.

25 Q At what point in time did you move from a

1 medical director to a senior medical director?

2 A It was after several years. I don't know  
3 exactly how long that would be. It was a couple of  
4 years.

5 Q Okay. And the role of senior medical  
6 director is the role you were in when you retired?

7 A No. Actually, I was senior medical  
8 director in actually therapeutic area later for  
9 analgesia, when I worked on Nucynta.

10 Then I transitioned to the infectious  
11 disease group, where I was a senior medical  
12 director, but I was in the infectious disease group,  
13 for about a year and a half.

14 In my last six months in the company, I  
15 worked on special projects. And at that point, I  
16 was a medical director.

17 Q How many medical directors were there in  
18 the opioid analgesia group when you started in 2000?

19 A Just one.

20 Q Just you?

21 A Yes.

22 Q How many senior medical directors were  
23 there when you started for the opioid analgesia  
24 group?

25 A There were none.

1 Q You were the first?

2 A I was the first medical director. And my  
3 supervisor -- and I don't remember what his title  
4 was. He may have been a group area lead or  
5 something like that, but...

6 Q Prior to hiring you to be the medical  
7 director for the opioid analgesia products at  
8 Janssen in 2000, was there someone else in that  
9 role?

10 A So, the medical affairs group really began  
11 in 2000. And at that point, the analgesia group was  
12 begun. My supervisor, at that time, Dr. Bruce  
13 Moskovitz, hired me based on my background and  
14 expertise.

15 And so, as I already testified, I was the  
16 first and only medical director at that point.

17 Q As a medical director at Janssen working  
18 with opioid analgesics, you worked with Duragesic  
19 and Nucynta?

20 A Yes.

21 Q What other opioids did you work with?

22 A Tramadol.

23 Q Tramadol.

24 All right. And when did Duragesic launch?

25 A So, Duragesic first came to the U.S.

1 market, I believe, in 1990. So, the product had  
2 been on the market for approximately 10 years before  
3 I joined the company --

4 Q And during those --

5 A -- in the U.S. Yeah.

6 Q And during those 10 years, there was no  
7 medical affairs group at Janssen?

8 A So, a lot of those activities were run by  
9 our R&D group. And the company had made a decision  
10 that they were going to develop a med affairs group  
11 to engage in the type of activities that ultimately  
12 became the responsibility of medical affairs.

13 So, the work was done, but it was done  
14 really by individuals in the R&D group.

15 Q By "R&D," you mean "research and  
16 development"?

17 A Yes, that's correct.

18 Q By "med affairs," you mean "medical  
19 affairs"?

20 A Correct.

21 Q Who was responsible in the R&D group for  
22 Duragesic during this 10-year period of time?

23 A I don't know. Because as I mentioned, that  
24 had predated my arrival at Janssen; so, I don't  
25 know.

1 Q Do you know whose decision it was to create  
2 a medical affairs group at Janssen?

3 A I don't.

4 Q You mentioned that Bruce Moskovitz hired  
5 you?

6 A Yes, that's correct.

7 Q What was his position when he hired you?

8 A So, I don't recall the title at that point.  
9 It would have been something like -- and again, this  
10 is -- this is from memory, and I don't have an exact  
11 thing that I can give you.

12 So, recollection would be something like a  
13 group director or something like that. But he led  
14 the group.

15 Q The medical affairs group?

16 A The medical affairs group for analgesia.

17 There were other medical affairs groups, as  
18 well, for different therapeutic areas.

19 Q Okay. You mentioned tramadol.

20 Did you work with Ultram?

21 A Yes. So, the active ingredient in Ultram  
22 is tramadol.

23 Q Did you work with any other tramadol  
24 products?

25 A I did. I worked with Ultracet, which was

1 tramadol and acetaminophen; and the extended-release  
2 tramadol called Ultram ER.

3 Q And can you please tell the jury what the  
4 active pharmaceutical ingredient in Nucynta is?

5 A So, Nucynta -- the active pharmaceutical  
6 ingredient in Nucynta is tapentadol.

7 Q Tapentadol.

8 And if I use the word -- or the  
9 abbreviation "API," you understand that means  
10 "active pharmaceutical ingredient"?

11 A Yes.

12 Q Okay. So, can you please tell the jury  
13 what the API for Duragesic is?

14 A So, the active opioid in Duragesic is a  
15 drug called fentanyl.

16 Q So, when you were working in the medical  
17 affairs group for analgesia, you were working with  
18 opioids containing the following APIs: Fentanyl,  
19 tramadol, and tapentadol?

20 A Correct.

21 Q Were there any others?

22 A Not to the best of my recollection.

23 Q Are any of these APIs synthetic APIs?

24 A Yes, they are.

25 Q Which ones?

1           A     Tapentadol is a synthetic opioid, and  
2     tramadol is a synthetic opioid.

3           Q     And fentanyl is a semisynthetic opioid?

4           A     That's correct.

5           Q     Has Janssen ever had, to your knowledge, an  
6     opioid that was neither synthetic nor semisynthetic?

7           A     I don't know. I don't know.

8                     And your question about fentanyl, I believe  
9     it's semisynthetic, but I would need to check on  
10    that.

11          Q     It might be synthetic?

12          A     It might be synthetic. Actually, my  
13    recollection is that it very well might be  
14    synthetic.

15          Q     So, fentanyl, tramadol, and tapentadol are  
16    all synthetic opioids?

17          A     Some degree of synthetic, yes.

18          Q     What do you mean by that?

19          A     Well, they either have to be synthetic or  
20    semisynthetic.

21          Q     Okay. Is there a reason why Janssen, to  
22    your knowledge, only manufactured and marketed  
23    synthetic opioids?

24          A     I don't know.

25          Q     All opioids, both nonsynthetic, synthetic,



1 and semisynthetic --

2 A I didn't hear the last thing, Counsel.

3 Q Pardon me?

4 A I didn't hear what you said, the last  
5 thing.

6 Q Pardon me. Let me start over.

7 A Sure.

8 Q All opioids, whether nonsynthetic,  
9 synthetic, semisynthetic, they're all treated the  
10 same as controlled substances, right?

11 A So, the medications that I worked on, which  
12 were Duragesic and tapentadol, were controlled  
13 substances of the C2 category. Tramadol initially  
14 was not scheduled, and later on it was scheduled.

15 Q And what schedule was it placed on?

16 A I would have to check. I want to think --  
17 I would say it was C4 for tramadol. The other two  
18 were C2, from the...

19 Q Is it your position that synthetic opioids  
20 are in any way safer than other types of opioids?

21 A So, the synthetic opioids carry the same  
22 risks as the natural occurring opioids, such as  
23 morphine.

24 Q Is it fair to say that -- new question.

25 Thank you.

1           While you were working in the med affairs  
2 group, did you work on any non-opioid-containing  
3 products?

4           A     Just so I can clarify the question. You  
5 mean when I was in the analgesia group?

6           Q     Yes.

7           A     Is that your question?

8                   Because I did testify that I worked in the  
9 infectious disease group.

10          Q     Fair enough. Let me restate.

11                   While you were working in the medical  
12 affairs group for analgesia --

13          A     Yes.

14          Q     -- did you work on any pharmaceuticals that  
15 did not contain an opioid?

16          A     Not directly. I provided consultation to  
17 the research and development group for another  
18 medication that was not an opioid. It was a  
19 biologic, but that was a compound that was  
20 eventually abandoned by the company.

21          Q     What was its intended use? What was it --

22          A     It was going to be used -- I believe the  
23 indication was for chronic pain, but I worked on it  
24 very peripherally and just provided some guidance to  
25 them based on my background and expertise.

1 But those activities were run predominantly  
2 by the research and development group, the R&D  
3 group.

4 Q Does Janssen manufacture any  
5 pharmaceuticals meant to treat chronic pain that are  
6 not opioids?

7 A Not that I'm aware of.

8 Q But Janssen has researched and attempted to  
9 develop non-opioid, chronic pain medications?

10 A There was one medication that they looked  
11 at.

12 Q What was it called?

13 A I don't remember the name now.

14 Q Do you know why it was abandoned?

15 A I don't.

16 Q Who would know that?

17 A I guess the people in the R&D group who  
18 would have worked on it.

19 Q And that's the R&D group that existed while  
20 you were an employee in the medical affairs group?

21 A That's correct.

22 Q And the R&D group no longer performed the  
23 medical affairs function it had performed before you  
24 arrived at Janssen?

25 A Right. So, just to clarify. The

1 activities from medical affairs that I talked about  
2 in the analgesic group were handed over to the  
3 medical affairs group in 2000.

4 Q But you still worked with the R&D group?

5 A Yes, I did. I provided consultation to  
6 them, as requested.

7 Q You also provided consultation to other  
8 departments or groups at Janssen, correct?

9 A Yes.

10 Q What were those groups?

11 A So, I provided support -- or, actually,  
12 consultation to our safety group, also called our  
13 pharmacovigilance group. I worked with our outcomes  
14 research group. I worked with our regulatory  
15 affairs group. These are, again, on issues related  
16 to analgesia, which was my primary function.

17 Those were a lot of the groups that I  
18 worked with.

19 Q You also worked with marketing, correct?

20 A Yes, that's correct, I did.

21 Q And with sales?

22 A Not with sales as much, but with marketing  
23 in the capacity -- in my capacity working on the  
24 promotional review committee and other and --  
25 interactions, as well.

1 Q Can you please explain to the jury what the  
2 outcomes research group at Janssen does?

3 A Yes. So, the outcomes research group are a  
4 group of individuals trained to analyze data from a  
5 variety of different sources. And some of the data  
6 sources that they may work on may be databases,  
7 looking at information which would be of interest  
8 clinically.

9 So, for example, they may look at the  
10 demographics of patients on certain types of  
11 medications, how those medications would be used.  
12 They would also look at data quality of life-type  
13 data that would come out of our clinical trials, et  
14 cetera.

15 So, that would be some -- not all of it,  
16 but some of the information that they would work on.

17 Q And the outcomes research group at Janssen  
18 also supports the marketing department?

19 A The outcomes research group generated data  
20 that we felt was clinically valuable and needed.  
21 Where we got feedback on our compounds is the type  
22 of information they would have.

23 I'm really -- need to get more  
24 clarification, Counselor, from what you mean by  
25 "supports."

1 Q Sure. Well, I was using your word. That  
2 was a word, actually --

3 A Sure.

4 Q -- that I picked up from you.

5 A Okay.

6 Q But my question is: The data generated by  
7 the outcomes research group could be used by  
8 Janssen, and was used by Janssen, in promotional  
9 material?

10 A So, actually, not very much, if at all.

11 So, the nature of the material that was --  
12 is included for promotional materials was dictated  
13 by quality of evidence or a level of evidence from  
14 FDA.

15 So, the data from our controlled clinical  
16 trials, a -- placebo-controlled trials, are data  
17 that we would have predominantly used in most, in  
18 our promotional materials. And that would have been  
19 the materials that a sales representative would have  
20 been able -- again, these would have to be  
21 company-approved materials. So, there would have  
22 been information that would have been reviewed by a  
23 committee, the promotional review committee. And  
24 the people on the committee were a physician.

25 It would have been -- we had legal

1 representation. We had somebody from regulatory  
2 affairs. We had somebody from our medical  
3 information group. And they would review the  
4 information to ensure it was fair balanced.

5 So, that's the type of information that  
6 would be used. It wasn't directly necessarily going  
7 out from outcomes research to marketing. It would  
8 have to go through a rigorous review process at the  
9 company.

10 Q And through that process, ultimately, the  
11 research from outcomes research could make its way  
12 into promotional material?

13 A My recollection was that very little, if  
14 any, of it actually did. There were many pieces  
15 that were reviewed. So, I would have to qualify my  
16 answers, as I've just done.

17 To the best of my recollection, that type  
18 of data did not find its way, for the most part,  
19 into promotional materials. It would have been  
20 really more from our clinical trials.

21 Q Why not?

22 A Because FDA defines the level of evidence  
23 that they say is appropriate to be used. And  
24 those -- their level of evidence that they define  
25 would be placebo-controlled trials.

1 Q And the FDA regulates the marketed --  
2 excuse me, new question.

3 The FDA regulates the branded promotional  
4 material that Janssen generates, right?

5 A That companies use, yes.

6 Q Including Janssen?

7 A Yes.

8 Q And the FDA does not regulate what's known  
9 as nonbranded marketing, right?

10 A I would need to check on that, to be  
11 honest.

12 Q Okay. You're not familiar with that?

13 A I don't know what the current state of the  
14 art is. I had retired, as I mentioned, in 2017; so,  
15 I don't know what current standards are from the FDA  
16 around those materials.

17 Q During your time at Janssen, the FDA did  
18 not regulate nonbranded promotional material,  
19 correct?

20 A That was my understanding.

21 Q Is the work of the safety or  
22 pharmacovigilance group at Janssen used in  
23 promotional material?

24 A I'm not sure exactly what you mean by that  
25 question. Could you clarify a little bit for me?



1 Q Sure. Let's break it down.

2 What did the safety or pharmacovigilance  
3 group at Janssen do?

4 A Right. So, they would have analyzed data  
5 that would have come in from -- either from  
6 consumers or from healthcare professionals and look  
7 and analyze that type of data.

8 They ultimately -- we had a -- we have a  
9 safety database called SCEPTRE, and they look at  
10 adverse events coming in from there, as well as  
11 adverse events coming in from FDA. There is an FDA  
12 database.

13 I don't know whether the pharmacovigilance  
14 group would have had an opportunity to look at the  
15 safety data from our clinical trials. I suspect  
16 that they do.

17 And those data actually would then be  
18 reviewed with FDA, and those -- that type of  
19 information, if FDA approved from our controlled  
20 clinical trials, would find its way in the  
21 promotional materials.

22 Hence is why I asked for the clarification  
23 of the question.

24 Q Well, let's talk about the  
25 pharmacovigilance group.

January 17, 2019

26

1           You mentioned SCEPTRE, right?

2           A     That's correct.

3           Q     Did the pharmacovigilance group have access  
4 to RADARS?

5           A     Yes, they did.

6           Q     Did they have access to DAWN?

7           A     I believe that they did.

8           Q     Okay. And they reviewed the data within  
9 those various databases or the data generated from  
10 them?

11          A     Yes.

12          Q     Did any of their work product from such  
13 reviews ever make its way into promotional material?

14          A     So, the DAWN data did find its way into one  
15 piece of promotional materials, and we heard about  
16 that from the FDA. We promptly took that out and  
17 contacted healthcare providers that we were told  
18 that we needed to take that out.

19                What was the -- I'm sorry, what was the  
20 other part of your question?

21          Q     Let's follow up on that right there.

22                Janssen received a warning letter from the  
23 FDA?

24          A     That is correct.

25          Q     About DAWN data?

1 A That's correct.

2 Q And the FDA found that, in its view,  
3 Janssen had used DAWN data to suggest that Duragesic  
4 was safer than other opioids, right?

5 A I don't believe that that was the claim.

6 Q Okay. What is your understanding?

7 A My understanding was that there was a  
8 mention of data from DAWN in the promotional piece.

9 Q And that's it?

10 A Yes. They were talking about the mention.  
11 I don't believe that comparative statements relative  
12 to other opioids were done. That's my recollection.

13 Q Your understanding is that you -- Janssen  
14 received a warning letter from the FDA simply  
15 because it mentioned DAWN data in promotional  
16 pieces?

17 A No. I think my understanding is that FDA  
18 commented on the fact that they believe that the  
19 DAWN data was not of a sufficient level of evidence  
20 to be placed in a promotional materials. We did not  
21 agree.

22 Q But you would agree that the DAWN data used  
23 in the promotional pieces were used to portray  
24 Duragesic in a positive light?

25 A We believed -- and my recollection was that

1 there was interest at the time of understanding  
2 information that could be used to look at mentions  
3 of abuse, especially for a population coming into an  
4 emergency room setting, which is where DAWN was  
5 done.

6 Q Did Janssen, during your time there, ever  
7 use any safety data from DAWN, RADARS, or SCEPTRE  
8 that portrayed Duragesic in a negative light?

9 A We didn't have data, that I was aware of.

10 And I developed the active surveillance  
11 methodology that showed low mentions -- that showed  
12 significant issues with abuse.

13 In fact, to my analysis -- and my team set  
14 up the active surveillance programs, to answer your  
15 question. And consistently, both for tapentadol and  
16 for Duragesic, really looking at it from, from the  
17 time that I was monitoring it, from the time I got  
18 to the company, but even looking back beyond that,  
19 there were low mentions of abuse for those  
20 compounds.

21 So, we didn't see the type of safety signal  
22 that I think you're trying to ask me about, if I'm  
23 understanding your question correctly.

24 Q And the FDA found that one of the problems  
25 with DAWN data is that it may not accurately capture

1 the safety hazards with particular drugs, right?

2 A As I had testified already, the FDA had  
3 indicated that the level of evidence that would be  
4 required to be in promotional material was not  
5 information that was in DAWN.

6 We thought it was important to put it in,  
7 because we had heard from experts around abuse that  
8 this was important data, and we thought it was  
9 important to share that with clinicians.

10 Parenthetically, in our risk management  
11 program, subsequently, FDA asked us to put DAWN data  
12 in. So, they must have thought the data was good  
13 enough to be a part -- and collected as part of the  
14 risk management program.

15 Q How many studies did Janssen conduct  
16 involving its opioids that were never published or  
17 released to the public?

18 A None.

19 Q Every single one of the studies that  
20 Janssen performed related to its opioids was either  
21 published or otherwise disclosed to the public?

22 A So, to the best of my understanding, all of  
23 the opioid analgesic studies, there was an attempt  
24 to publish, to answer your question, to try and get  
25 it into the public domain.

1           It may have been in a journal article, or  
2   it may have been presented in a professional meeting  
3   as an abstract or a post or...

4           Q     But there were none that were never either  
5   published or presented?

6           A     For the studies that I was aware of, my  
7   recollection was -- and the studies that I was also  
8   responsible for -- those studies were -- saw the  
9   light of day in the public domain, in some fashion,  
10  as I mentioned.

11          Q     And you were involved in -- new question.  
12                 You just said you were responsible for some  
13  studies?

14          A     Correct.

15          Q     And you helped to create or craft what  
16  those studies were intended to study?

17          A     Not completely.

18          Q     Okay. Explain that, please.

19          A     Yeah. So, there were studies that were  
20  ongoing before I had gotten to the company.

21          Q     Understood.

22          A     Yeah.

23          Q     Once you were at the company, any new study  
24  that you were involved in and responsible for, you  
25  could decide what that study was intended to

1 research, right?

2 A I didn't hear the last part, I'm sorry.

3 Q You were involved in determining what each  
4 study was intended to research?

5 A I was part of a team that made that  
6 decision. It was not a decision made unilaterally  
7 by me.

8 Q And by "part of a team," you mean a team of  
9 other Janssen employees?

10 A Yes.

11 And there would have been feedback from  
12 some of the external experts that -- who have -- who  
13 would provide some information to us and the types  
14 of information that people thought would be  
15 important to do.

16 Q And Janssen sells its pharmaceutical -- new  
17 question.

18 Janssen sells its opioids with the intent  
19 of making a profit, right?

20 A Janssen markets its opioids for the idea  
21 that we want to make sure that the right patients  
22 get the right medications to treat their pain and  
23 that prescribers use the medications as prescribed  
24 to ensure that they're used safe and effectively.

25 Q A couple of things in there.

1 First, I used the word "sell," you used the  
2 word "market."

3 Are you using those words synonymously?

4 A Let me clarify my statement.

5 Janssen's intent is to ensure that its  
6 products are used as directed per package insert and  
7 that individuals are using the product  
8 appropriately.

9 Q All right. Janssen is a for-profit  
10 company, correct?

11 A Yes.

12 Q Is Janssen a publicly traded company?

13 A Yes.

14 Q Janssen has a duty to its shareholders,  
15 correct?

16 A Yes, it does.

17 Q And Janssen develops, manufactures, and  
18 sells pharmaceuticals in order to make a profit?

19 A Janssen has a duty to its shareholders.

20 And to follow up on your comment,  
21 Counselor, if I may, Janssen also operates under the  
22 J&J credo. And the credo sets the business ethics  
23 forward on how the company operates. The duty to  
24 their shareholders is certainly part of the credo,  
25 and it's actually the last portion of the credo.



1 Q It's number four, right?

2 A That's correct.

3 The first one is the responsibility -- I'm  
4 paraphrasing -- is responsibility to physicians and  
5 nurses, to mothers and fathers, and to other -- and  
6 to patients.

7 So, we recognize that we have a duty to  
8 shareholders, but we conduct our business in an  
9 ethical manner and ensure that our products are used  
10 safely and effectively.

11 Q If Janssen were not profitable, it couldn't  
12 exist for very long, could it?

13 A Correct. What we were always taught was,  
14 if you take care of the first three portions of the  
15 credo, the fourth one takes care of itself.

16 So, if you work to take care of patients  
17 properly, you take care of the environment, you  
18 take -- make sure the employees are well treated,  
19 and all of those things are good business practices  
20 and translate into a profit.

21 And then protecting our patients is our  
22 first responsibility.

23 Q Your testimony is that Janssen has done all  
24 of those things?

25 A Yes, it has.

1 Q Okay. You are also aware that people have  
2 died from taking Janssen's opioids?

3 A I am aware of the fact that there are  
4 overdoses that take place.

5 I'm aware that we have worked with  
6 regulatory authorities, through my time at Janssen,  
7 to ensure that we had appropriate product labeling  
8 and that the drugs were used as intended in the  
9 patient populations for whom they were intended.

10 But there are instances where patients  
11 died.

12 Now, some of the deaths that you're  
13 referring to may have been individuals who also had  
14 co-morbid conditions. So, for example, the deaths  
15 associated with people who were end-stage cancer  
16 patients, those patients may have been on the  
17 Duragesic patch and died, as well.

18 So, it's -- while it's true that there were  
19 deaths, one would need to look and see what was  
20 overdose; and one may have been due to coexisting  
21 medical conditions, as well.

22 Q So, you are aware that there is currently  
23 an opioid crisis in this country, right?

24 A Yes.

25 Q All right. Are you aware that there is an

1 opioid crisis in the state of Oklahoma?

2 A I -- I'm not specific around the crisis in  
3 Oklahoma, but I'm aware of the opioid crisis in the  
4 United States.

5 Q And the opioid crisis is a crisis of  
6 addiction, right?

7 A So, my understanding is the crisis of  
8 substance abuse. And I don't know if it's a crisis  
9 of addiction. I'd have to read more and think more  
10 about that.

11 But certainly of substance abuse, I'm aware  
12 of that.

13 Q Okay. So, the opioid crisis is a crisis of  
14 substance abuse, right?

15 A Yes.

16 Q It's a crisis of overdose, right?

17 A Yes.

18 Q It is a crisis that has upended the lives  
19 of many Americans, right?

20 A Yes.

21 Q It's a crisis that has been very expensive  
22 for various stakeholders, right?

23 A I assume so.

24 Q Okay.

25 MR. DUCK: Okay. Let's take a quick break.

January 17, 2019

36

1 THE VIDEOGRAPHER: We're off, 9:41.

2 (Recess taken.)

3 THE VIDEOGRAPHER: Back on, 9:50.

4 Q When you were working at Janssen,  
5 Dr. Vorsanger, what work did you do to help address  
6 the opioid crisis?

7 A So --

8 MR. LIFLAND: Object to the form of the  
9 question.

10 A Could you clarify a little bit what you  
11 mean by that for me?

12 Q Janssen didn't want this crisis to occur,  
13 right?

14 A We want to make sure that our patients were  
15 receiving our medications in a safe and effective  
16 manner.

17 Q And this crisis shouldn't have occurred,  
18 should it?

19 A I can't comment on what happened with the  
20 crisis because I don't know what the causes of the  
21 crisis are.

22 Q Well, surely Janssen undertook efforts to  
23 try to reverse the opioid crisis?

24 A Janssen ensured that its products were  
25 being used in a safe and effective manner.

1 And to answer your question about what  
2 Janssen did to monitor, we had surveillance  
3 methodologies that went on for our pharmacovigilance  
4 group, our safety group, and those have been going  
5 on since the product came to market in the U.S.

6 In addition to that, I started what we  
7 called active surveillance programs to monitor, as  
8 well. And I can go into detail, if you'd like to me  
9 [sic], about those, as well.

10 Q Yeah. So, that brings up a good point.

11 Monitoring is a passive task, right?

12 A Well, sir, there are, there are two -- we  
13 believe -- and we have defined two types of  
14 monitoring.

15 Q One is active, and one is passive?

16 A That's correct, yes.

17 Q Okay. So, how long did Janssen engage in  
18 passive monitoring of abuse of its opioid products?

19 A So, what we would call passive  
20 monitoring -- and to ensure -- so, everybody  
21 understands what I mean by that, we mean by the work  
22 that would have been done by a pharmacovigilance  
23 group.

24 I know that's the term that's used, but  
25 it's important for people who maybe don't work in

1 the area, in my mind, to understand that it's really  
2 not passive, necessarily. It's passive in the  
3 nature of how the information comes in.

4 It comes in from consumers; it comes in  
5 from healthcare professionals and other sources, as  
6 well. And that information is analyzed through our  
7 pharmacovigilance group. They also look at journal  
8 articles that are published, as well.

9 The other type is active surveillance, and  
10 those are methodologies that I had helped to  
11 institute in the company fairly early on from when I  
12 started.

13 You recall, I testified that I started in  
14 2000.

15 Q Can you give us a year?

16 A The dates are approximate.

17 I started looking at how we could begin to  
18 monitor our opioids based on the current  
19 methodology.

20 So, in the early 2000 -- and again, dates  
21 are approximate, as I just mentioned -- we worked  
22 with learned individuals who know about abuse,  
23 people like -- groups like Bensinger Dupont, PDRC,  
24 and other companies, as well, to get an  
25 understanding of what they had -- you know, what

1 they knew about. In those days, it was just  
2 Duragesic, our transdermal fentanyl patch. And  
3 again, that continued in addition to what we  
4 described as the passive surveillance.

5 Later on, when RADARS became available --  
6 and I would think that was in the timeframe of about  
7 2005, 2006 -- and again, the dates are  
8 approximate -- Janssen was a -- started and took and  
9 was a subscriber to the RADARS program, as well.

10 When the RADARS program took place, not  
11 only did we put fentanyl into that program -- and my  
12 recollection, Counselor, was that that was  
13 introduced even before we were required to do so by  
14 the FDA.

15 But in addition to --

16 Q Required to do what by the FDA?

17 A To do surveillance activities of that  
18 nature by the FDA.

19 Q When did the FDA start requiring Janssen to  
20 start doing surveillance?

21 A Later on -- it might have been around '05  
22 or '06, but we had that in plan -- we had that in --  
23 plans to do that anyway.

24 We also included the tramadol, which we  
25 were not required to monitor. We rolled that from

1 the independent steering committee from tramadol.

2 And later on, what I did, as part of my  
3 responsibilities, as I built out the program, was, I  
4 had asked that RADARS give me a background snapshot  
5 of abuse before the tapentadol immediate release --  
6 that's Nucynta -- actually even came into the U.S.  
7 marketplace.

8 Because we were bringing in -- other opioid  
9 analgesic in, we wanted to make sure that we  
10 understand what the situation was.

11 So, those were done, again, a bit -- if I  
12 could describe it as a bit above and beyond what we  
13 were asked to do.

14 Q What does "RADAR" stand for?

15 A People ask me, and I'm embarrassed to tell  
16 you that I don't know. We can look it up. It's,  
17 it's an acronym for something, and I don't remember  
18 what it is.

19 Q RADARS is not public information, right?

20 A So, I haven't been associated with RADARS  
21 for quite a while. RADARS does have an annual  
22 meeting, where some of the information may be  
23 available to the people invited from the public to  
24 do it.

25 But the information around the individual



1 branded compounds was not public information. That  
2 was information provided to the pharmaceutical -- to  
3 the subscribers.

4 Q And Janssen, while you were there,  
5 considered the RADARS data related to its opioid  
6 products to be confidential?

7 A In fact, I had the -- in fact, I had the  
8 idea that we think -- we thought it was important to  
9 share our data with people. We thought that this  
10 was important information, and because it wasn't  
11 widely available.

12 So, one of my publications -- and again,  
13 I'm paraphrasing on the title -- was 31 months of --  
14 that was for the first 31 months of information  
15 around abuse of tapentadol. Again, it's Nucynta.  
16 That was published.

17 So, we made an effort to try and share  
18 RADARS data so that it would be publicly available  
19 to people.

20 Q Janssen pays a lot of money for -- while  
21 you were there, Janssen paid a lot of money for  
22 RADARS data, right?

23 A Janssen felt it was important to monitor  
24 our opioids, as we discussed. So, there was a  
25 subscriber fee that the company paid.

1 Q Over a million dollars a year?

2 A I don't know the precise amount, but it  
3 was -- it's somewhere around there.

4 Q Over \$100,000 a month, right?

5 A Again, my recollection was about a million,  
6 Counselor, but it certainly could have been more.

7 Q So, "RADARS" stands for "Researched Abuse,  
8 Diversion and Addiction-Related Surveillance"  
9 System, correct?

10 A That sounds correct.

11 Q How long did Janssen subscribe to RADARS?

12 A I can only comment on what I know. We had  
13 started subscription when it became available for  
14 the opioids, as I've described.

15 When the U.S. rights for tapentadol were  
16 sold to another company -- and we didn't continue  
17 that with tapentadol. And I was not responsible for  
18 Duragesic after about 2005 or 2006, when the product  
19 went off-patent. So, I -- there were other  
20 individuals at the company doing that. So, they may  
21 have continued the monitoring.

22 So, I'm unable to answer the question of  
23 how long each of the compounds had been monitored by  
24 RADARS.

25 Q The medical affairs group no longer worked

1 on Duragesic after it went off-patent?

2 A There was a different group, a different  
3 medical affairs group at Janssen that worked on  
4 Duragesic.

5 Q Is there a generic medical affairs group  
6 and a branded medical affairs group?

7 A So -- just so I'm clear -- and I don't know  
8 that I was correct on what I just said.

9 So, I had worked on Duragesic until about  
10 2005 and '6. Those responsibilities were passed to  
11 another physician in medical affairs. And later on,  
12 the responsibilities for tapentadol were transferred  
13 to a different medical affairs group within Janssen,  
14 to the CNS group.

15 I continued to monitor for tapentadol with  
16 RADARS. And it's my belief that the other medical  
17 affairs group monitored for Duragesic.

18 So, that's, that's my understanding of the  
19 situation.

20 Q "CNS" stands for "central nervous system"?

21 A Yes, that's correct.

22 Q Why didn't Janssen publish the RADARS data  
23 related to Nucynta on its website every month after  
24 it got it?

25 A I was unaware about the fact that Janssen

1 published RADARS data on its website every month.

2 Q No. My question is: Why didn't Janssen?

3 A Oh, why didn't?

4 I don't know the answer to that. I  
5 think -- we think it was important to provide the  
6 information. And we were one of the first to  
7 actually provide what we did know about tapentadol  
8 when it came out.

9 The information on RADARS that came for  
10 both Duragesic and tapentadol were shared with the  
11 FDA in our safety reporting. They got that type of  
12 information. So, we were certainly providing that  
13 information to regular authorities -- regulatory  
14 authorities.

15 Q Why did Janssen not make RADARS data  
16 related to Nucynta available to the public  
17 untouched?

18 A I can't -- I don't know specifically why.  
19 I think we just wanted to make sure that the data  
20 would be put in a format that would be  
21 understandable for people, and we thought the best  
22 way to do that was through the publication process.

23 The publications were done with RADARS as  
24 authors, where the scientists who generated the data  
25 would be able to explain it.

1           So, to put raw data, without an explanation  
2           on how to do that, sometimes can be problematic,  
3           because people may not necessarily understand it.  
4           And we thought the venue of putting it through, as  
5           I've already mentioned, publications in a way that  
6           people can understand it was a -- was the right way  
7           to do it.

8           Q     There are a lot of good researchers that  
9           don't work for Janssen, right?

10          A     That's, that's correct.

11          Q     There are a lot of good researchers that  
12          don't work for RADARS, correct?

13          A     There are people who -- yes.

14          Q     And why didn't Janssen provide the RADARS  
15          data untouched to the public so that those  
16          researchers could also look at that data and draw  
17          their own conclusions?

18          A     Well, if individuals were interested in  
19          getting RADARS data, then they certainly had an  
20          opportunity to reach out to the company and make a  
21          request for that type of information.

22          Q     And isn't it true that Janssen would only  
23          share that type of information if a confidentiality  
24          agreement was entered into?

25          A     I, I, I don't know that to be the case.

January 17, 2019

46

1 Q I'm going to hand you what we'll mark  
2 Exhibit 1 to your deposition.

3 (JAN-MS-0214093 through 094 was  
4 marked as Vorsanger 1 for  
5 identification, as of this  
6 date.)

7 MR. DUCK: If you'll pass --

8 MR. WEISBAND: Actually, I need to look at  
9 it, first.

10 MR. DUCK: My intent is that it was for  
11 y'all.

12 MR. FIORE: That's fine.

13 Q All right. Do you see your name at the top  
14 of this email?

15 A I do.

16 Q All right. This is an email chain between  
17 you and several other Janssen employees, right?

18 A That's correct.

19 Q Have you seen this email between the time  
20 that you wrote it and now?

21 A No, sir, I have not.

22 Q All right. This email was written in 2008,  
23 right?

24 A Yes. So, it appears to be.

25 Q And it relates to RADARS, correct?

1 A Correct.

2 Q At the bottom of the page, we see an email  
3 from Margaret Quinn.

4 Who is Margaret Quinn?

5 A She is a member -- or was a member, at that  
6 time, of the state government affairs group.

7 Q For Johnson & Johnson?

8 A Yes, that's right.

9 Q She didn't work directly for Janssen,  
10 correct?

11 A I believe so, yes.

12 Q She did or she did not work directly --

13 A Yeah, she did.

14 Q Okay. And her signature block says  
15 "Johnson & Johnson."

16 Did she work for Johnson & Johnson or  
17 Janssen or both?

18 A She worked for Johnson & Johnson.

19 Q In her email, you'll see there's a bracket  
20 where she states your name?

21 A Yes.

22 Q Do you see that?

23 She says, "Gary, I assume RADARS is the  
24 monitoring surveillance program you have in place.  
25 Can you offer any clarity?"

January 17, 2019

48

1 Right?

2 A Correct.

3 Q Did I read that right?

4 A Yes.

5 Q And then you responded to Margaret in the  
6 email above, correct?

7 A Right.

8 Q You say, "Hi Margaret," and then explain  
9 RADARS.

10 A Right.

11 Q Can you please read your explanation?

12 A Sure. "We purchased data from RADARS  
13 for" --

14 Q Sorry, can you start above, above that.  
15 The word "yes" is the first --

16 A Oh, yes, of course. Yes.

17 "RADARS is a network that provides  
18 information on abuse and diversion of prescription  
19 pain medications on a subscription basis to  
20 participating pharmaceutical companies about their  
21 products."

22 Q Thank you.

23 A Shall I continue?

24 Q Please.

25 A "We purchase data from RADARS for Duragesic



1 and our tramadol-containing products. We would not,  
2 for example, be able to provide data on branded  
3 prescription pain medication such as OxyContin."

4 Q Okay. Let's stop there. Why not?

5 A The arrangement that we had per contract  
6 with RADARS is that pharmaceutical companies would  
7 be able to purchase branded -- information for their  
8 own branded products but not information for the  
9 branded products from other companies.

10 So, as I've stated here, we would not be in  
11 a position to get data on OxyContin, Purdue's  
12 products, but we would have information on generic  
13 oxycodone.

14 We -- conversely, Purdue, would not be  
15 getting information directly on Duragesic, but they  
16 would be getting information in general on generic  
17 fentanyl, which would include information on  
18 Duragesic.

19 And as -- to clarify, also, the generic  
20 information on oxycodone would have lumped in there  
21 the OxyContin, but we wouldn't have  
22 OxyContin-specific information.

23 Do you want me to continue?

24 Q Well, let me -- a couple of follow-up  
25 questions.

1 A Sure.

2 Q For Janssen's subscription to RADARS, did  
3 it request all of the generic opioids RADARS data?

4 A We would be provided that as part of the  
5 data that RADARS provided for us.

6 Q So, you would receive, at Janssen, the  
7 RADARS data related to Janssen's branded opioids and  
8 the RADARS data for all opioid APIs?

9 A That RADARS was monitoring.

10 Q Was RADARS not monitoring certain opioid  
11 APIs?

12 A So, I don't know what, what they were  
13 monitoring and what they weren't monitoring.

14 But the subscription included, as I've  
15 already described, the drugs that they were actually  
16 monitoring.

17 Q Okay. Can you start with the next  
18 sentence.

19 A Sure.

20 "RADARS is completely independent of PhRMA.  
21 Dr. Richard Dart heads up the RADARS program and has  
22 accompanied us on occasion to discuss RADARS  
23 findings as they relate to tramadol."

24 Q What did you mean by, "RADARS is completely  
25 independent of PhRMA"?

1           A       We -- PhRMA doesn't have influence. RADARS  
2       collects the data, analyzes the data, and provides  
3       the data back based on their scientists looking at  
4       it and their interpretation, and that's the  
5       information that's provided to PhRMA.

6           Q       Janssen pays RADARS over a million dollars  
7       a year for that data, right?

8           A       To do the -- to accumulate the information,  
9       analyze the information, and provide their  
10      scientific understanding of the information in a  
11      report to Janssen.

12          Q       Do you know Richard Dart?

13          A       Yes, I do.

14          Q       And you've worked with Richard Dart, right?

15          A       I have.

16          Q       Okay. If you'll read the paragraph that  
17      starts "One of the success" --

18          A       Sure.

19          Q       Okay.

20          A       "One of the successes of our recent  
21      interaction in Oklahoma was that we were able to  
22      reach out to the state representative by  
23      teleconference and provide him with information  
24      needed. If there is a requirement for data and we  
25      can provide it by phone, then it would be easier

1 than having to pull a team together and make a trip  
2 to Nebraska."

3 Q Okay. Do you recall what's being discussed  
4 here about the State of Oklahoma?

5 A My recollection was that there was a  
6 request from the State of Oklahoma -- and I don't  
7 recall by whom -- to provide information that the  
8 company had on tramadol.

9 And my understanding is that that request  
10 would have come through the state, the state affairs  
11 representative to Oklahoma. And again, I don't know  
12 who that was at this point.

13 Q Do you know who Richard Ponder is?

14 A Yes, I do know Richard Ponder, but I didn't  
15 remember his name.

16 So, he might have reached out and said, "Do  
17 you have any information around what we know about  
18 abuse of tramadol for the State of Oklahoma?"

19 And the way I had set it up was, we wanted  
20 to make sure that the scientists who generated the  
21 data, wherever possible, could come out with us to  
22 explain their findings.

23 So, Dr. Dart headed up the RADARS program.  
24 And so, either he or another member of the  
25 scientific advisory board at RADARS would accompany

1 us -- again, as requested by the State -- to provide  
2 information about it.

3 And here, we have some state-specific  
4 information, as well.

5 Q And in particular, this Oklahoma discussion  
6 revolved around the scheduling of tramadol, right?

7 A Yes. There was a request for information  
8 on what was known about the abuse of tramadol.

9 Q And the higher an opioid is on DEA's  
10 schedule, the more restricted it is, right? So, for  
11 instance, a Schedule II drug would be more  
12 restricted than a Schedule III drug?

13 A That's correct.

14 Q And for purposes of making its  
15 pharmaceutical drugs accessible to the public,  
16 Janssen would prefer, if the data supports it, that  
17 its pharmaceuticals be on lower schedules as opposed  
18 to higher schedules?

19 A My recollection for -- having worked there  
20 and where we were, was we wanted to ensure that  
21 decisions were made in an evidence-based manner.

22 Tramadol had initially been approved by the  
23 FDA with an unscheduled status. I believe there was  
24 a period of monitoring that went on, that the  
25 company was required to do as part of the

1 requirements.

2           The company continued to monitor for abuse  
3 of tramadol after it was required to do so. And we  
4 felt that what needed to happen was, if there was a  
5 change for any reason in the abuse of the compound,  
6 then it would be reflected appropriately in how the  
7 drug would be handled, but that we wanted to make  
8 sure that decisions that were made were  
9 evidence-based, that we had -- they looked at the  
10 information available and to decide.

11           Q     You would agree that Janssen viewed the  
12 scheduling of its opioids as a threat?

13           A     I don't.

14           Q     You would agree that Janssen viewed the  
15 up-scheduling of any of its opioids as a threat?

16           A     No, actually, I don't.

17           Q     Okay. I'm going to hand you Exhibit 2.

18                                 (JAN-MS-02149085 through 086 was  
19                                 marked as Vorsanger 2 for  
20                                 identification, as of this  
21                                 date.)

22           MR. DUCK: You're just going to stick on  
23 that path?

24           MR. WEISBAND: What's that?

25           MR. DUCK: You're just going to stick on

1           that path? I'm mean, that's their courtesy  
2           copy. You're welcome to, but...

3           MR. WEISBAND: I'd like to review the  
4           document before I pass it to them.

5           MR. DUCK: Doing my best for you, Mark.

6           Q     You're ready?

7           A     Yes, sir, I am.

8           Q     Okay. Thank you.

9           A     Well, I also wanted to comment, if I may,  
10          on a follow-up of your question, because I think  
11          it's important. And you were asking about  
12          scheduling.

13          There were instances where --

14          Q     So, I've got some questions about this  
15          document.

16          A     Which I would follow your lead, Counselor.  
17          Whatever you'd like.

18          Q     Yeah. Thank you very much.

19          A     Okay.

20          Q     Your counsel will have an opportunity, if  
21          he wants, to ask you some questions later.

22          A     Very good. Okay.

23          Q     So, this is another email chain involving  
24          you and Bruce Moskovitz, right?

25          A     Yes.

1 Q On the next page, there are a few other  
2 people that we see on the email.

3 And this is from Christopher Lepore, right?

4 A Let me find the email.

5 Q Who is that?

6 A Christopher Lepore is someone who worked in  
7 state government affairs.

8 Q For Johnson & Johnson?

9 A Yes.

10 Q Thank you.

11 He states, "I just received the Nevada  
12 Board of Pharmacy's agenda for their meeting  
13 March 5th and 6th. They plan to discuss the  
14 scheduling of tramadol and may take action. This is  
15 the first time the issue has been brought up in  
16 Nevada. Larry Pinson, the executive director of the  
17 BOP, is on vacation until next Tuesday. In the  
18 meantime, I left a message for the board's general  
19 counsel. We'll need to meet with Larry next week.  
20 Any help you can provide, Gary, would be  
21 appreciated."

22 Did I read that correctly?

23 A Yes.

24 Q He's referring to you there, right?

25 A Yes, I believe so.



1 Q And you responded to the email, but only to  
2 Bruce Moskovitz, correct?

3 A Let me read the front.

4 Q The bottom email on the front page.

5 A (Perusing document.)

6 Okay.

7 Q All right. You say, "Bruce, we now have a  
8 request from Nevada and Nebraska." Right?

9 A Yes.

10 Q What kind of request?

11 A Presumably a request for information on  
12 what we know about -- from our data in RADARS at  
13 that time about --

14 Q Sorry, excuse me. Go ahead.

15 A -- to provide that type of information to,  
16 in this case, individuals in both Nevada and  
17 Oklahoma.

18 Q So, the reason that a state may want to  
19 know about RADARS data for a particular drug is to  
20 determine which schedule that drug should be on?

21 A So, my understanding is the states, when  
22 they reached out to us, wanted to know what  
23 available scientific data we might have been able to  
24 share with them, as part of their decision-making  
25 processes.

1 Q And the abusability of a drug or the  
2 occurrence of abuse for a particular drug is an  
3 important piece of information?

4 A So -- yes. So, the abusability of a drug  
5 is defined by its schedule status. But information  
6 on how the drug might be abused and mentions of  
7 abuse would be important information.

8 Q So, a drug -- an opioid that's on  
9 Schedule II is considered to be more abusable than a  
10 drug on Schedule III?

11 A The abusability of a drug is defined in  
12 law. And so, a Schedule II would be more abused,  
13 potentially abusable than a Schedule III or a  
14 Schedule IV.

15 Q And RADARS data is some evidence of the  
16 abusability of a particular drug, right?

17 A Yeah. The RADARS data has information on  
18 how a product would be used -- to be abused.

19 Q Thank you.

20 Can you read the second paragraph here of  
21 your response, that starts "Richard Ponder"?

22 A "Richard Ponder indicated that while we  
23 have done well in Oklahoma with the representative  
24 there, the Oklahoma Board of Pharmacy is threatening  
25 to schedule tramadol again. Ted Cicero and I were

1 out there several years ago and were able to address  
2 their concerns by providing data from the ISC" --  
3 which is the independent steering committee for  
4 tramadol.

5 Q Who is on the independent steering  
6 committee, do you recall?

7 A I don't know that I have all of the  
8 members. Dr. Ted Cicero was, Dr. James Inciardi  
9 was.

10 Q And they work for RADARS; is that right?

11 A So, they worked, initially, on the  
12 independent steering committee for tramadol. When  
13 RADARS was formed, it's my understanding that they  
14 went out to work, and many, if not all, of those  
15 people comprised the scientific advisory board at  
16 RADARS.

17 So, the answer to your question is, yes,  
18 but I don't know if everybody did.

19 Q When you and Ted Cicero went out to  
20 Oklahoma to address the Board of Pharmacy's  
21 concerns, where did Ted Cicero work?

22 A He worked at Washington University. He  
23 amassed --

24 Q In St. Louis?

25 A Yes. He amassed that information as one of

1 the data sources for RADARS. He was also on the  
2 scientific advisory board for RADARS.

3 And as I had testified earlier, when we had  
4 requests for information from RADARS, we went out  
5 with individuals who were knowledgeable in  
6 generating data and could really explain the data  
7 best.

8 Q Did he work at all for RADARS at that time?

9 A In 2008, I -- he might have. I don't know.  
10 Because RADARS was up for awhile, and, as I  
11 mentioned earlier, Purdue had formed it, and he may  
12 have been working at the original RADARS at that  
13 point.

14 But I think somebody from Purdue could  
15 better answer that than me, than I could.

16 Q Do you know if Oklahoma's Board of Pharmacy  
17 ever scheduled tramadol?

18 A I believe that, later on, the State of  
19 Oklahoma did schedule it, but I don't know that for  
20 a fact.

21 Q The abusability of a drug is a constant. A  
22 drug is abusable unless it's reformulated; the  
23 abusability is constant, right?

24 MR. LIFLAND: Object to the form of the  
25 question.

1           A     The abusability of a drug may change with  
2     time, and it's important to monitor the drug to see  
3     how the product may have been changed.

4                     The abusability of the drug is also  
5     determined by the delivery system of the drug.

6                     So, for example, fentanyl is a drug that's  
7     potentially quite abused. But in a system, for  
8     example, such as the Duragesic patch, where there is  
9     a controlled delivery of pharmaceutical-grade  
10    fentanyl, the rate of rise into the -- first the  
11    medication going into the body and the rate of rise  
12    until it gets into the central nervous system is  
13    slow. So, therefore, the drug tends to be less  
14    desirable to the people who intend to abuse a  
15    medication.

16                    So, abusability needs to be understood, as  
17    I've just said, in terms of the delivery system.  
18    And that's why we need to monitor, to see if there  
19    are changes in it.

20            Q     If the delivery system stays the same for a  
21    particular opioid, the abusability of that opioid  
22    product is constant?

23            A     Well, sir, if --

24                    MR. LIFLAND: Object to the form of the  
25    question.

1           A       Addicts are individuals who will find ways  
2       in which they can. So, there -- it may be, for  
3       example, that a product was abused in a certain way  
4       for a period of time, but addicts may sometimes find  
5       new and different ways that they do it.

6                       So, I think it would be important, as I've  
7       already mentioned -- and in all of the publications  
8       that I have, you'll see at the end it will say  
9       something like "continued monitoring is warranted,"  
10      just for that reason, to ensure that we understand  
11      how products are abused.

12                     And if the patterns of abuse change, that  
13      we, at Janssen, were in a position to understand  
14      that and educate individuals on how these drugs are  
15      abused.

16                     MR. DUCK: Object as nonresponsive.

17           Q       Sir, I'm asking you a yes-or-no question.

18           A       Yes.

19           Q       You're welcome to explain that later, when  
20      your counsel takes you on redirect.

21                     I'm asking you a yes-or-no question. Do  
22      you understand that?

23           A       So --

24                     MR. LIFLAND: Objection.

25           Q       Let me ask you again.

1           If the delivery system stays the same for a  
2     particular opioid product, the abusability of that  
3     product is constant?

4           A     No, sir, it's not.

5           Q     Okay. You were part of a team, along with  
6     Ted Cicero, that visited Oklahoma, right?

7           A     Yes.

8           Q     You addressed their concerns, right?

9           A     Yes.

10          Q     And tramadol was not scheduled, correct?

11          A     Not at that time, sir.

12          Q     And your understanding is that today it is  
13     scheduled, right?

14          A     That's what I believe.

15          Q     Thank you.

16                 You'll see that Bruce Moskovitz responds to  
17     your email just above the one we were looking at.

18                 Do you see that?

19          A     Yes, I do.

20          Q     Can you read his response, please.

21          A     Sure.

22                 "Is there a SWAT team that we can put  
23     together with Ted Cicero and whatever source at  
24     RADARS, perhaps under a retainer system, that would  
25     allow them to mobilize as soon as a threat is

January 17, 2019

64

1 detected with minimal oversight on our part? It  
2 seems to me that this is how we routinely respond  
3 anyway, except that we always start from ground  
4 zero."

5 Q All right. And was Bruce Moskovitz your  
6 supervisor?

7 A Yes, he was.

8 Q He sent this email to you, correct?

9 A I believe so, yes.

10 Q Did Janssen ever put together such a SWAT  
11 team?

12 A No, sir, they didn't.

13 Q Who is Edgar Adams?

14 A Edgar Adams was another member of the  
15 independent steering committee. As I testified  
16 earlier, I couldn't remember everyone, and he was  
17 another individual who worked at RADARS, and he was  
18 also, as I've just said, on the independent steering  
19 committee.

20 Q Are members of the independent steering  
21 committee paid for their services?

22 A I don't remember what the arrangement was  
23 at the time.

24 Q How much money did Janssen pay Ted Cicero  
25 over the time that you were there?



1 A I don't know.

2 Q But Janssen did pay him?

3 A He was paid for his time.

4 Q Thanks.

5 And you mentioned earlier that you had  
6 worked with Richard Dart before, right?

7 A Yes.

8 Q And he was the head of RADARS, correct?

9 A Yes.

10 Q You also worked with Richard Dart and Ted  
11 Cicero on research, correct?

12 A They were involved in some of the  
13 publications that we had, yes.

14 Q I'll hand you what we'll mark as Exhibit 3.

15 (JAN-MS-00641019 through 022 was  
16 marked as Vorsanger 3 for  
17 identification, as of this  
18 date.)

19 (Whereupon, a discussion was  
20 held off the record.)

21 Q Okay. This is an email chain that starts  
22 out between you and Richard Dart, right?

23 A Yes.

24 Q So-- and I'm looking at the second --  
25 excuse me, the third page. There's an email from

1 you at the bottom of that page.

2 Now, this email chain deals with research  
3 that was done by Dr. Ted Cicero and Dr. Jim  
4 Inciardi, right?

5 A I'll need to review the email for a moment,  
6 Counselor.

7 (Perusing document.)

8 Okay.

9 Q In the email that you sent, you'll see  
10 there are some italicized words in there?

11 A Yes.

12 Q You see those?

13 He says -- you say to Richard Dart, who is  
14 the head of RADARS -- in your email, you say, "It  
15 appears that Drs. Cicero and Inciardi have the  
16 ability to publish manuscripts with our data at any  
17 time and for any purpose, and that we have no  
18 control over how and where our data will be used."

19 Did I read those words right?

20 A Yes.

21 Q And those were words that you italicized in  
22 your email, correct?

23 A Correct.

24 Q This was a concern of yours, wasn't it,  
25 sir?

1 A Um --

2 Q It's a yes-or-no question, sir.

3 A Yes, it was.

4 Q At the end of this paragraph, you say that,  
5 "We believe that publication of this manuscript  
6 represents a violation of the confidentiality of our  
7 data."

8 Correct?

9 A Yes.

10 Q Now, above that, Richard Dart explains that  
11 RADARS started as a Purdue project, correct?

12 A I have to read the email.

13 Q Specifically the third paragraph.

14 A Yeah, let me read it.

15 (Perusing document.)

16 Okay.

17 Q So, just a couple of questions on this one.

18 Richard Dart is explaining that there may  
19 be some access to Janssen's data because a license  
20 was given when Purdue was still running RADARS,  
21 right?

22 A So it seems.

23 Q So, why, if you know, did Purdue sell  
24 RADARS or -- you know, I don't actually know how it  
25 was transferred.

1 But Purdue no longer runs RADARS, right?

2 A Correct.

3 Q Now it's run by a different organization,  
4 correct?

5 A Yes.

6 Q Are you familiar with the name of that  
7 organization?

8 A I believe it was Denver Health.

9 Q The Rocky Mountain Poison & Drug Center?

10 A Yes, as a part of Denver Health.

11 Q Okay. Do you know how RADARS passed from  
12 Purdue to Denver Health?

13 A No, I do not.

14 Q But at this point in time, Denver Health  
15 ran RADARS?

16 A Correct.

17 Q The second-to-last sentence is, "As for  
18 your other comments, please be careful. Email is  
19 discoverable."

20 Right?

21 A That's what it says.

22 Q Was the -- do you have any understanding of  
23 why it is he wrote that sentence?

24 A I do not.

25 Q On the next page, flipping forward in time,

1 page 2, you respond to Richard Dart, and you say,  
2 "By way of violation of our confidentiality, we are  
3 referring to the fact that two of the authors on the  
4 paper never obtained confidentiality agreements from  
5 us to review the PriCara data captured within  
6 RADARS."

7 Right?

8 A Yes.

9 Q What is PriCara?

10 A PriCara was one of the operating companies  
11 that ultimately became Janssen, that ultimately  
12 became Janssen.

13 Q What was PriCara responsible for?

14 A PriCara was responsible for -- I'd have to  
15 look and see. Certainly Duragesic was one of its  
16 responsibilities.

17 Q When it was PriCara, was it owned by  
18 Johnson & Johnson?

19 A Yes, it was.

20 Q But PriCara was rolled into Janssen?

21 A Yes, as I mentioned, it was one of the  
22 operating companies of J&J that rolled into Janssen.

23 Q Richard Dart responds, "Your email is very  
24 concerning to me. I don't usually get emails like  
25 this from you, although I do from others. I have

1 spoken with Jim, and I do not think he thinks that  
2 he wrote this in a favorable manner" --

3 Excuse me, let me say that again.

4 Richard Dart says, "I have spoken with Jim,  
5 and I do think he thinks that he wrote this in a  
6 favorable manner."

7 A Right.

8 Q "He is amenable to further discussion and  
9 revision."

10 Did I read that right?

11 A Yes.

12 Q On the next page, Richard Dart sends  
13 another email to you, correct?

14 A Yes.

15 Q And again, this is all in 2007, right?

16 A Correct.

17 Q Richard Dart says, "Gary, I've just  
18 reviewed -- finished reviewing the paper in detail.  
19 I've made numerous suggestions for Jim, and he  
20 sounded willing to make them, the last time I spoke  
21 with him. However, experience has taught me no one  
22 reads the paper more carefully than the company  
23 involved. If you have comments, I would like to get  
24 them. In fact, I think the best approach would be  
25 for a conference call of all three of us -- Jim,

1 you, and me -- so, that Jim can get a feel for what  
2 gets the attention of the subscriber."

3 That's you, the subscriber, Janssen, right?

4 A That's what I'm assuming he's referring to.

5 Q Yep.

6 He continues, "We have to understand, like  
7 most investigators, Jim writes in a vacuum, never  
8 hearing the concerns of the company whose products  
9 he studies."

10 Did I read that right?

11 A Yes.

12 Q And you never provided any comments to Jim  
13 or Richard, right?

14 A The email I have above would have been a  
15 comment that I would have given to Dr. Dart.

16 Q Which was that you wanted to take a  
17 hands-off approach?

18 A Yes.

19 Q And you can tell from the emails that  
20 Richard Dart sent that he was concerned about not  
21 upsetting Janssen, right?

22 MR. LIFLAND: Object to the form of the  
23 question.

24 A I think -- in a partnership with Janssen, I  
25 think that Dr. Dart wanted to ensure that the

1 relationship went according to what we had  
2 contractually, and that it was done in a manner that  
3 reflected that.

4 Q And he said that Jim didn't think that he  
5 wrote an article that made Janssen look bad,  
6 correct?

7 MR. LIFLAND: Object to the form of the  
8 question.

9 A That's what it looked like he had  
10 mentioned.

11 Q Yup. Because in the top email, Richard  
12 Dart sends another email to you.

13 Can you please read the first two sentences  
14 of that email.

15 A Yes. I think -- this is from Dr. Dart to  
16 me in '07.

17 "Okay. I think that will work fine. I  
18 don't think the manuscript will make Duragesic look  
19 bad. I'm asking that Jim emphasize the fact that  
20 generic is diverted even if the magnitude isn't as  
21 big as he expected yet. He gets to the point that  
22 all opioids are abused and we need to address the  
23 whole issue rather than pick on certain drugs."

24 Q Thank you.

25 And we mentioned earlier that you actually



1 paid for this data from RADARS.

2 I would just like for you to review  
3 Exhibits 4 and 5 for me and confirm that.

4 (JAN-MS-02102600 through 602 was  
5 marked as Vorsanger 4 for  
6 identification, as of this  
7 date.)

8 Q Here is Exhibit 4.

9 You'll see that both of the exhibits I'm  
10 handing you are, indeed, signed by you.

11 (JAN-MS-02102624 through 626 was  
12 marked as Vorsanger 5 for  
13 identification, as of this  
14 date.)

15 Q And they are for the years 2013 and 2014.

16 A (Perusing document.)

17 Q All right. In the 2013 document,  
18 Exhibit 4, this is -- reflects an amendment to the  
19 contract between Janssen and Rocky Mountain Poison &  
20 Drug Center for the RADARS data, correct?

21 A Yes.

22 Q And it's fully executed, as you see the  
23 signatures on the last page, correct?

24 A Correct.

25 Q And on the second page, there is a section

1 2B, which references the "Compensation" section,  
2 right?

3 A Yes.

4 Q And can you please tell me how much Janssen  
5 agreed to pay for RADARS data in 2013?

6 A Yes. "Subscriber" --

7 Do you want me to read the whole thing or  
8 just the number?

9 Q You can just tell me the number.

10 A Sure. 1,392,114.

11 Q And how much was that per month?

12 A \$116,000 per month.

13 Q And that's what Janssen agreed to, and you  
14 got that information from Exhibit 4 that you're  
15 looking at?

16 A Yes.

17 Q On the 2014 contract, we see a similar  
18 format, again, executed by you on the last page.

19 And in section 2B, you'll see the  
20 "Compensation" section, right?

21 A Correct.

22 Q And how much did Janssen pay for RADARS  
23 data in 2014?

24 A \$1,392,114.

25 Q How much was that per month?

1 A \$116,009.50 per month.

2 Q And you answered my question by looking at  
3 Exhibit 5, right?

4 A Yes, that's correct.

5 Q Who is Nat Katz?

6 A Nat Katz is Nathaniel Katz.

7 Q And how do you know him?

8 A From working in the area of analgesia.  
9 Dr. Katz is a pain specialist, neurologist, I  
10 believe, by training.

11 Q He is not an employee of Janssen?

12 A He was not certainly when I worked with  
13 him.

14 Q However, he did do some work for Janssen,  
15 right?

16 A Yes.

17 Q And he was a paid researcher for Janssen?

18 A He was a paid consultant for us.

19 Q And he published papers about Janssen's  
20 products, correct?

21 A He was one of the authors on papers about  
22 our products.

23 Q He's been a lead author on papers for  
24 Janssen's products?

25 A I would need to check that, but I can

1 certainly answer that he was an author on those  
2 papers.

3 Q You'd agree with me that Schedule II  
4 opioids are addictive?

5 A I do.

6 Q And you would agree with me that, as a  
7 manufacturer of opioids, Janssen should always  
8 stress the risk of addiction?

9 A Yes, I do.

10 Q And you would agree with me that Janssen  
11 should never omit that information about the risk of  
12 addiction?

13 A The information on addiction should be made  
14 available through communications with prescribers as  
15 it is in our product package inserts and other  
16 sources, as well.

17 Q And you would agree with me that opioid --  
18 Schedule II opioids are dangerous?

19 A If they're -- so, if the medications are  
20 used as prescribed in appropriately selected  
21 patients under the care of a healthcare professional  
22 who is knowledgeable on how to administer those  
23 medications, they can be very safe and effective.

24 If they're used not according to the  
25 product label or used in other ways or if

1 individuals seek to abuse or divert the product or  
2 tamper with it, then it can be -- lead to dangerous  
3 consequences.

4 Q Is it your testimony that, when a patient  
5 uses an opioid under a doctor's care and as  
6 prescribed, that it is a safe product?

7 A If it's used as prescribed, it is -- again,  
8 with follow-up and care from a physician, yes, it  
9 can be -- it is a safe product.

10 Q Is it your testimony that a patient who  
11 takes opioids under the care of a physician as  
12 prescribed will not get addicted?

13 A No, it's not. There is a known rate of  
14 what we call iatrogenic addiction. And I can define  
15 that, if you wish, Counselor.

16 Q Iatrogenic addiction is when a patient gets  
17 addicted taking a medicine as prescribed under a  
18 doctor's care?

19 A Or taking medication, yes.

20 Q So, you're aware that iatrogenic addiction  
21 can occur with Janssen's opioid products?

22 A Iatrogenic addiction can occur. The rates  
23 are known. Yes.

24 Q What are the rates?

25 A The rates from the published literature

1 that we have seen are, when you -- and as per our  
2 conversation, if it's used as directed in  
3 appropriately selected patient population, the rates  
4 can be approximately 1 to 4 percent.

5 Those rates do go up for individuals who  
6 may have added complicated past medical histories or  
7 medical histories. And by that I mean, if they are  
8 substance abusers or have a history of mental  
9 health, then the rates of iatrogenic addiction can  
10 be higher.

11 And, in fact, they're labeled that way.  
12 That type of information does exist in the product  
13 label, I believe, of Duragesic.

14 Q How does Janssen identify those different  
15 patient populations?

16 A Janssen doesn't. That's the responsibility  
17 of the healthcare professional who engages in a  
18 discussion with their patients as part of a --  
19 taking a careful medical history and identifying and  
20 discussing those risks with the patient, pointing  
21 out why those risks are important in terms of the  
22 medication, to stay in touch with them and help them  
23 where they can.

24 Q You would agree with me that the risk of  
25 addiction is different for each patient that walks

1 into a doctor's office, fair?

2 A I do.

3 Q You went to medical school, right?

4 A Yes, sir, I did.

5 Q What years?

6 A 1980 to 1984.

7 Q Did you receive any training in addiction?

8 A I don't recall.

9 Q Well, you'd agree with me that,  
10 historically, medical schools have not taught  
11 addiction science?

12 A So, I don't know whether addiction  
13 science -- what it would have been, depending on  
14 that period of time.

15 But I think they would have discussed the  
16 fact that these were Schedule II opioids and that  
17 they were, therefore, addictive by nature of their  
18 scheduling.

19 Q Well, when you went to medical school, you  
20 learned that opioids should be prescribed rarely,  
21 didn't you, sir?

22 A I don't remember what I was told about how  
23 they would be prescribed.

24 Q There was no opioid crisis in the '80s,  
25 correct?

1 A "There was no"?

2 Q Opioid crisis in the '80s?

3 A Not to the best of my knowledge.

4 Q The opioid crisis started when opioids  
5 began to be prescribed for the treatment of chronic,  
6 nonmalignant pain; isn't that right?

7 MR. LIFLAND: Object to the form of the  
8 question.

9 A I'm not certain when the opioid crisis  
10 actually began.

11 We know, for example, that there was  
12 illegal fentanyl that was coming into the country at  
13 different periods of time, and I don't know when  
14 those dates started.

15 So, the question of when did it begin is  
16 one, Counselor, that I don't know the answer to. I  
17 don't know if it blossomed or grew or when it  
18 actually started, and I don't know -- so, I can't --  
19 I'm unable to comment on that.

20 Q Why don't you know that?

21 A Because I don't think the epidemiology of  
22 it has been traced far enough back to really  
23 understand it, or at least I haven't read about it  
24 or heard about it.

25 Q Why haven't you looked into it?



1 MR. LIFLAND: Object to the form of the  
2 question.

3 A Because the issues that we have is to  
4 ensure that our products are prescribed safely,  
5 effectively, and as directed per our product package  
6 inserts.

7 And what we did -- and I did was I worked  
8 at the company, was -- as I've already mentioned and  
9 testified, was to monitor our products for abuse.

10 Q Well, Janssen's products are part of the  
11 opioid crisis, right?

12 A No, sir, I don't agree with that.

13 Q You don't believe that Janssen's products  
14 are abused?

15 A I believe that Janssen's products can be  
16 abused.

17 Q You've seen it in the RADARS data.

18 A We saw -- and -- we -- for all of the  
19 reviews that we had, not only for the RADARS data  
20 but subsequently from the Inflexxion data, we saw  
21 low mentions -- consistently saw low mentions of  
22 abuse for Duragesic as well as for tapentadol.

23 Q Who defines "low"?

24 A Low number of mentions is low.

25 Q You?

1           A     Relative to some of the other, other  
2     opioids that we're seeing.

3           Q     All right.

4           A     I think that's generally acknowledged by  
5     experts in the field.

6           Q     Just so we're clear, when you say there are  
7     low mentions of Janssen's drugs Duragesic and  
8     tapentadol, those are your words?

9           A     Those are the words --

10           MR. LIFLAND: Object to the form of the  
11     question.

12           A     Those are the words of individuals who are  
13     knowledgeable outside of Janssen and outside of me,  
14     experts.

15           Q     What does "low" mean?

16           A     "Low" means -- I don't have a number to  
17     give you. But if I look at, for example, some of  
18     the other medications, bractive [sic] abu -- mentions  
19     of abuse are higher.

20           Q     The fact that other medications are abused  
21     more does not mean that Janssen's medications have a  
22     low rate of abuse --

23           A     Well, sir, I can --

24           MR. LIFLAND: Object to the form of the  
25     question.

1 Q -- right?

2 A I can show you the data, but I don't -- if  
3 that's something that's discussed.

4 Q Let me ask my question again.

5 The fact that other opioids are abused more  
6 doesn't mean that Janssen's opioids have a low rate  
7 of abuse?

8 A No, sir. My statement about low rates --  
9 and I don't use the word "rate," I use "mentions."

10 The mentions of abuse are low, and I can  
11 show you that in the RADARS data, and I can show you  
12 that in the commentary from Inflexxion data.

13 Q Well, see, you use the word "mentions"  
14 because it's important that you use precise language  
15 in the pharmaceutical industry, right?

16 A Correct.

17 MR. LIFLAND: Object to the form of the  
18 question.

19 A Yes.

20 Q And you don't want to say something that  
21 isn't true in the pharmaceutical industry, correct?

22 A No, sir.

23 Q But Janssen did say to prescribers and in  
24 other material that Janssen's products have a low  
25 rate -- a low -- excuse me.

1 Janssen did say to prescribers and in other  
2 materials that Janssen's products had low mentions  
3 in the reported abuse data, correct?

4 MR. LIFLAND: Object to the form of the  
5 question.

6 A I would like to see that documentation.

7 Q You're aware of that, right?

8 A Sorry?

9 Q You're aware of that, that Janssen made  
10 those statements?

11 A I'd like to see those statements.

12 Q I'm not asking -- you're aware that --

13 A Not --

14 Q -- Janssen has gotten in trouble for doing  
15 that?

16 A Not in promotional materials that were  
17 shared with prescribers, that I'm aware of.

18 Q Are you familiar with a Joranson study that  
19 involved the DAWN network?

20 A Yes, I am.

21 Q Do you know whether or not that information  
22 was shared with prescribers?

23 A So, the DAWN data, as I believe I had  
24 testified earlier this morning, was in a promotional  
25 piece that was, that was reviewed. It was discussed

1 with the FDA.

2 The FDA indicated that the level of  
3 evidence was not high enough to be used in a  
4 promotional venue. The piece was removed.

5 And Janssen subsequently reached out to  
6 individuals who may have received the piece and  
7 corrected it.

8 Q All right. Tell us about the Joranson  
9 study you said you were familiar with.

10 A Well, there were two studies. There was an  
11 initial study that came out by Joranson -- the  
12 Joranson, I believe, was in the timeframe of 1990 to  
13 1995, or thereabouts.

14 Q All right. Let's talk about that one  
15 first.

16 A Okay.

17 Q What was your understanding of what that  
18 study showed?

19 A It showed low mentions of abuse -- low  
20 mentions of ER admissions for fentanyl-containing  
21 products and for oxycodone, as well.

22 Q All right. And you mentioned that it  
23 looked at DAWN mentions from 1990 to 1995?

24 A I believe -- that's to the best of my  
25 recollection.

1 Q I'll submit to you that I think it was  
2 1996.

3 A Okay.

4 Q Do you know when OxyContin hit the market?

5 A Those data, to the best of my knowledge,  
6 did not capture OxyContin, because I don't think the  
7 product was on the market at that point, for that  
8 first DAWN data -- the Joranson article.

9 Q Right. OxyContin hit the market in 1996,  
10 correct?

11 A I don't recall the year, but I know it was  
12 not on the market for -- with those data.

13 Q And you'd agree with me that OxyContin is  
14 one of the culprits of the opioid crisis today,  
15 correct?

16 MS. NEWSOME: Objection to form.

17 MR. LIFLAND: Object to the form of the  
18 question.

19 A No, sir, I don't.

20 Q You don't think that OxyContin has anything  
21 to do with the opioid crisis today?

22 A I would need to understand a little bit  
23 more about what -- about the oxy -- about the opioid  
24 crisis that we discussed and what the components  
25 are.

1           So, I'm not in a position at this point to  
2     comment upon it.

3           Q     All right.  Sir --

4           A     I don't feel I have enough data at this  
5     point.

6           Q     -- you are the senior medical director of  
7     medical affairs -- excuse me, the senior medical  
8     director in the medical affairs group for analgesia  
9     at Janssen, right?

10          A     Yes, sir.

11          Q     And you don't feel like you're in a  
12     position to understand the components of the opioid  
13     crisis?

14          A     I believe that the components of the opioid  
15     crisis are complex.

16          Q     You haven't tried to understand them?

17          A     I have started to understand them.  I think  
18     people are still trying to figure out what it is and  
19     what the components are.

20                 I think there are elements of the opioid  
21     crisis -- for example, illegal fentanyl and other  
22     substances.  So, I think there's complexity, as I  
23     testified earlier, in the crisis.

24          Q     And you can't answer my questions because  
25     you don't fully understand the opioid crisis, right?

1           A     I believe that the opioid crisis is  
2     something that would require more information before  
3     we can begin to address it.

4                 So, right now, there's no evidence, that  
5     I'm aware of, that I have read, identifying  
6     specifically which -- about pharmaceutical  
7     companies.

8                 What I do know, as you asked me, is that  
9     the medications that I monitored, the Janssen  
10    products, had low mentions of abuse.

11           Q     You can't answer my questions about the  
12    opioid crisis because you don't understand the  
13    opioid crisis, yes or no?

14           A     I --

15                 MR. LIFLAND: Object to the form of the  
16    question.

17           A     I don't understand the complexity of the  
18    opioid crisis.

19           Q     Is Purdue responsible for the opioid  
20    crisis?

21                 MS. NEWSOME: Objection to form.

22                 MR. LIFLAND: Object to the form of the  
23    question.

24           A     I think I had indicated to you already that  
25    the complexity of the opioid crisis was such that



1 it's not clear what the cause of it -- the root  
2 cause of the opioid crisis is.

3 Q As -- in your opinion as a former senior  
4 medical director at Janssen overseeing opioid  
5 analgesia medical research, do you believe that  
6 Purdue bears even 1 percent of responsibility for  
7 the opioid crisis?

8 A I'm not familiar --

9 MR. LIFLAND: Object to the form of the  
10 question.

11 A I'm not familiar with Purdue's processes  
12 and what they did and how they acted.

13 And as I indicated to you -- so, I'm not  
14 able to understand -- I'm not able to respond to the  
15 question to really say what they did or did not do.

16 Q Were you ever familiar with what Purdue did  
17 and did not do?

18 A Well, I -- having -- not having worked at  
19 the company, not having interacted with people very  
20 much at the company, and now knowing their processes  
21 and how they did what they did, I didn't feel like  
22 I -- and I still today don't feel like I'm in a  
23 position to comment on that.

24 Q Did you ever work on any recall studies?

25 A Yes, sir, I did.

1 Q Okay. Explain to the jury what a recall  
2 study is.

3 A So, if there was a problem with a product,  
4 then --

5 Q I think we might be talking about two  
6 different things, and that's my fault.

7 Have you ever worked on any studies that  
8 looked into physician recall of promotional  
9 messages?

10 A Could you explain that more for me?

11 Q Sure.

12 It's a survey of physicians to see what  
13 they specifically recall about sales  
14 representatives' visits.

15 A Oh, you're talking about memory recall.

16 Q Memory recall.

17 A Okay. As opposed to recalling a product  
18 because of a problem.

19 Q Exactly.

20 A Okay. Thank you for clarifying.

21 Q Did you work on any memory-recall studies  
22 while you were at Janssen?

23 A Not to the best of my recollection.

24 Q You're aware that Janssen conducted  
25 memory-recall studies?

1           A       I'm not aware of it. They might have.  
2       That may be something that sales groups do, to try  
3       and see how good their messages are. But I don't  
4       have specifics about it at Janssen.

5           Q       So, you're not aware that Janssen performed  
6       a memory-recall study that asked physicians what  
7       they remembered about Purdue's salesforce messages?

8           A       Not that I recall.

9           Q       Would you have seen that, had it been done?

10          A       Possibly.

11          Q       You would agree with me that Purdue has  
12       been accused of aggressively overpromoting  
13       OxyContin?

14               MS. NEWSOME: Objection to form.

15               MR. LIFLAND: Object to the form of the  
16       question.

17          A       I believe that there was something in the  
18       lay press about that, but I don't follow that, and I  
19       don't know the specifics about that.

20          Q       Okay. Are you aware of a 2003 GAO report  
21       about Purdue's marketing tactics?

22          A       Not that I recall.

23          Q       Are you aware that Purdue pled guilty to  
24       federal criminal felonies for misbranding OxyContin  
25       in 2007?

1 MS. NEWSOME: Objection to the form.

2 A I'm not aware of the specifics around that.

3 As I -- but as I have just testified, I heard  
4 something from the lay press about this.

5 Q So, you do recall that?

6 A I recall an article -- an article in the  
7 lay press, but I don't have the specifics about what  
8 happened.

9 Q Did Janssen not attempt to learn any  
10 lessons from what Purdue did?

11 MS. NEWSOME: Objection to form.

12 A I'm not, I'm not understanding the  
13 question. I'm sorry, Counselor.

14 Q When one of your competitors that  
15 manufactures and markets opioids is -- either pleads  
16 guilty to or is found guilty of a crime, Janssen  
17 doesn't look into what that company did?

18 MR. LIFLAND: Object to the form of the  
19 question.

20 A So, I don't know what the company did.

21 Q Why don't you know, is my question?

22 A Because I would not have --

23 MR. LIFLAND: Object to the form of the  
24 question.

25 A -- I would not have been the individual at

1 the company who would have been responsible to look  
2 into those types of activities.

3 Q There are lessons to be learned there.

4 You would agree with that, right?

5 MR. LIFLAND: Object to the form of the  
6 question.

7 A I would not be the person to be in a  
8 position to do that, as a medical director. That  
9 would be something that might be handled by other  
10 people with the company.

11 Q I'm just asking Gary Vorsanger, sitting  
12 here today --

13 A Yes, sir.

14 Q -- another competitor pleading guilty to  
15 federal crimes could provide some valuable insight  
16 to a pharmaceutical company about what not to do,  
17 correct?

18 MR. LIFLAND: Object to the form of the  
19 question.

20 A I think the individuals at the company who  
21 would be looking and doing those types of analysis  
22 would -- are not me.

23 My responsibilities at the company were,  
24 again, to the development of clinical trials and to  
25 monitor, as I've already testified, around abuse.

1 And that's, that's where -- that was the focus of  
2 where I conducted my time.

3 Q So, you can't say whether or not Janssen  
4 did exactly the same things that Purdue did?

5 A Well, I know --

6 MR. LIFLAND: Object to the form of the  
7 question.

8 A -- from my time at Janssen, working there  
9 for 16 years, and sitting here today as a witness of  
10 facts, that I did not witness any kind of behavior  
11 that I thought was not exemplary.

12 I think they act with ethics and a  
13 behavior -- in the area of the opioid analgesic that  
14 I did, I didn't see any type of negative behavior.

15 Q Not once?

16 A No, sir, not around the opioids, that I  
17 recall.

18 Q You never had to discipline any of the  
19 employees in the medical affairs group?

20 A For the individuals working on the opioid  
21 analgesics? Is that your question?

22 Q Yes, sir.

23 A No, sir, I did not.

24 Q You don't think that the FDA sending  
25 Janssen warning letters about its promotion of

1     opioids is bad behavior or reflects bad behavior?

2             MR. LIFLAND:   Objection to the form of the  
3             question.

4             A     The FDA entered in a discussion with the  
5     company.  We, as I already testified, felt that the  
6     data would be valuable to individuals who work in  
7     opioids.

8             And when we were told by FDA that it was  
9     inappropriate, we pulled the piece and, as I've  
10    already testified, contacted individuals to tell  
11    them what had happened.

12            Q     You disagreed with the FDA?

13            A     We thought the data was important, but we  
14    respected the FDA's understanding and decision of  
15    what they wanted in terms of the level of evidence.  
16    And when that became clear, that the information  
17    from the DAWN data did not reflect the level of  
18    evidence that they were interested, as I've just  
19    said, we pulled the piece.

20            Q     Do you recall a study performed by Janssen  
21    entitled "Fen USA 71"?

22            A     Yes, I do.

23            Q     What was that study?

24            A     That was a study looking at patient  
25    preference in individuals, in patients who were

1 either treated with Duragesic or with OxyContin.

2 Q Is pain a disease, sir?

3 A So, I need you to clarify that question a  
4 little more for me.

5 Do you mean acute pain or chronic pain?

6 Q Is chronic pain a disease?

7 A I believe that it is.

8 Q And do you believe that there is no  
9 underlying disease state that causes chronic pain?

10 A No, I think that there certainly can be  
11 underlying diseases that cause chronic pain, as  
12 well.

13 Q Chronic pain is a symptom of another  
14 disease, correct, sir?

15 A There are people who believe that it's a  
16 symptom. There are other people who think that it  
17 may be a disease itself, with other manifestations.

18 Q Does Janssen employ anybody in the medical  
19 affairs group who believes that chronic pain is a  
20 symptom?

21 A I don't know. I would have to canvass all  
22 the people who worked on it. I don't know that.

23 Q Janssen should not only hire medical  
24 affairs experts who share all of Janssen's views,  
25 right?



January 17, 2019

97

1 MR. LIFLAND: Object to the form of the  
2 question.

3 A I think Janssen needs to hire people who  
4 are qualified and have the medical background and  
5 expertise to be able to work effectively with their  
6 medications.

7 Q You're a man of science, right?

8 A Yes.

9 Q You don't just go along with the company  
10 line, do you?

11 MR. LIFLAND: Object to the form of the  
12 question.

13 A I understand the company line, and I  
14 actually agree with the company line, because their  
15 basic premise is to ensure that patients get the  
16 medications that they need and deserve, and the  
17 medications need to be prescribed and used  
18 responsibly.

19 Q So long as doing that is profitable, right?

20 MR. LIFLAND: Object to the form of the  
21 question.

22 A No, sir.

23 As I had already -- as I had already  
24 testified earlier today, we operate under the  
25 Johnson & Johnson credo, and we have a

1 responsibility to our patients as -- and to make  
2 sure that they get the very best that they can from  
3 our products, that the products are used safely and  
4 effectively.

5 Q Who are Janssen's patients?

6 A Well, it depends on the product that we're  
7 talking about.

8 Are you referring, sir, to chronic pain?

9 Q Yes.

10 A So, those would be individuals who would  
11 suffer from a variety of chronic painful conditions.

12 Q And you agree that Janssen has a  
13 responsibility to those patients?

14 A Yes.

15 Q Have you ever heard the abbreviation "CDS,"  
16 C-D-S?

17 A I'm not sure what that stands for.

18 Q You've never heard that before?

19 A Well, I don't know. In what context, sir?

20 Q Well, what do you think it stands for in  
21 this context, in this deposition?

22 MR. LIFLAND: Object to the form of the  
23 question.

24 A I don't know.

25 Q You've never heard the phrase "controlled

1 and dangerous substance"?

2 A I have not.

3 Q You didn't know that opioids were referred  
4 to as CDSs?

5 A I did not.

6 Q Why didn't you know that?

7 A I, I --

8 MR. LIFLAND: Object to the form of the  
9 question.

10 A I don't know. I just -- I did -- I have  
11 not heard that used for opioids.

12 Q Well, you don't think opioids are  
13 dangerous, do you?

14 A No, sir. I think if they're used  
15 inappropriately, they certainly can be dangerous,  
16 and I testified to that extent.

17 Q And you don't think addiction is dangerous,  
18 do you, sir?

19 A I think addiction can be dangerous, yes,  
20 absolutely.

21 Q You don't think it's dangerous in every  
22 circumstance?

23 A I think addiction -- well, if addiction is  
24 treated and under control, that's different from  
25 untreated addiction.

1 But addiction is a condition that can be  
2 quite dangerous, yes.

3 Q Can -- should Janssen's patients who are  
4 addicted to Janssen's products continue taking those  
5 products?

6 A That would be --

7 MR. LIFLAND: Object to the form of the  
8 question.

9 A The decision to continue a medication or  
10 not to continue a medication is one that needs to be  
11 made with a patient in conjunction with the  
12 healthcare provider.

13 Q You are a healthcare provider -- or were,  
14 right?

15 MR. LIFLAND: Object to the form of the  
16 question.

17 A Yes, sir, I am -- I was.

18 Q You have an MD?

19 A Not --

20 I beg your pardon?

21 So, I do have a medical degree. I was a  
22 healthcare provider at one point. And I know, as a  
23 healthcare provider, that the decision on what  
24 medications patients need to take is a decision that  
25 a -- is a personal decision that's made between a

1 patient and a healthcare provider.

2 Q All right. Can you please explain to me  
3 the circumstances under which you, as a healthcare  
4 provider, would determine your patient was addicted  
5 to a particular opioid and continue that patient on  
6 that same opioid at the same dose?

7 A Well, I would need to understand --

8 MR. LIFLAND: Object to the form of the  
9 question.

10 A I would need to understand the specifics.  
11 So, by that, I mean --

12 Q You mean there are situations where that's  
13 appropriate?

14 A Well, if a person, for example, needed  
15 opioid analgesia for a certain reason where other  
16 types of medications, lesser medicines were not  
17 appropriate, then we would maybe try and try other  
18 types of opioid analgesics, if that was appropriate,  
19 switch from one type to another --

20 Q Not my question, sir.

21 My question was: Can you please explain to  
22 me a situation where it's appropriate, as a  
23 physician --

24 A Sir --

25 Q -- to understand that your patient is

1 addicted to a specific opioid product and continue  
2 that patient on that specific opioid product?

3 A Well, I wasn't --

4 MR. LIFLAND: Please let him finish his  
5 answers.

6 A I was explaining it. So, if I might have a  
7 moment, please.

8 So, while certainly immediately, when you  
9 see that someone is addicted to a medication, the  
10 first inclination would be get them off that  
11 medication, for sure.

12 Your question to me was: Can you come up  
13 with a situation where you may continue them on it?  
14 That's your question.

15 So, if lesser pain medications were not a  
16 viable option, then we may be in a position where we  
17 need to think about opioids.

18 Now, if someone had severe allergic  
19 reactions or other types of situations where they  
20 didn't tolerate other types of opioids, then one  
21 might be stuck in a situation where the patient  
22 needs to continue on it.

23 Now, having said that, though, that  
24 individual would be someone who I would put into  
25 extensive psychological counseling. There are other

1 support groups that I would have. I would -- if the  
2 person had a family, I would work with them. And I  
3 would find ways to continue to have them safely use  
4 the medication and to help them control their  
5 addiction at the same time.

6 Q All right. So, in your opinion, sir, there  
7 are situations where you think it's appropriate for  
8 addicted patients to continue using opioids?

9 A They would be --

10 MR. LIFLAND: Object to the form of the  
11 question.

12 A They would -- given the scenario that I  
13 just reviewed for the jury, then that could happen.

14 But in medical practice, in general, we  
15 would certainly try and get the patient off that  
16 opioid; and if lesser means were possible, we would  
17 potentially try and get them off the opioid  
18 analgesics altogether, if that was possible.

19 Q What's worse, addiction or chronic pain?

20 MR. LIFLAND: Object to the form of the  
21 question.

22 A This would be a case-by-case thing, and I  
23 think we would really need to understand many, many  
24 factors. I don't think there is a blanket, specific  
25 thing that I can send an email out to everyone:

1 "This is better or worse than this."

2 I think we really need to take it on an  
3 individual basis with the individual patient.

4 Q Is addiction a disease?

5 A I believe that it is.

6 Q And you would agree with me that today,  
7 based on what you know, there are people who are  
8 addicted to Janssen's opioid products? They may be  
9 generic now, they may not be owned by Janssen, but  
10 there are people who are addicted to them?

11 MR. LIFLAND: Object to the form of the  
12 question.

13 A There may be -- I don't know who those  
14 people are, but they may be addicted.

15 Q Is that okay with you?

16 MR. LIFLAND: Object to the form of the  
17 question.

18 A I'm not understanding what you're asking  
19 me.

20 Q Let's back up.

21 When you worked at Janssen, you were aware  
22 that there were people addicted to the very opioid  
23 products that you worked on, correct?

24 A There likely were some people who had  
25 addiction to some of these products, yes.



1 Q And surely you were not proud of that fact,  
2 sir?

3 MR. LIFLAND: Object to the form of the  
4 question.

5 A Addiction is a known complication. It's  
6 described for opioid analgesics, and patients who  
7 become addicted on these medications need to be  
8 treated for those medications. They need to be  
9 cared for by people who are knowledgeable in how  
10 opioids should be used, and they need to be  
11 knowledgeable how to treat patients when they become  
12 addicted.

13 Q When Janssen learned that patients were  
14 addicted to some of their medications, did Janssen  
15 do anything to determine what prescriptions were  
16 prescribed to addicts?

17 MR. LIFLAND: Object to the form of the  
18 question.

19 A I, I -- I don't know the answer to that  
20 question.

21 I think if people reached out to the  
22 company to get help on how to care for patients,  
23 then, where possible, we tried to provide care, not  
24 only to the patients but to the prescribers, by  
25 providing medical education, reviewing package

1 inserts, and going through that type of information.

2 Q Did Janssen ever donate the money that it  
3 received from improper opioid prescriptions?

4 MR. LIFLAND: Object to the form of the  
5 question.

6 A I don't know the answer to that question.

7 Q Janssen makes money off of prescriptions,  
8 whether they're appropriate or inappropriate, right?

9 MR. LIFLAND: Object to the form of the  
10 question.

11 A I don't know the answer to that, as well.

12 Q Why not?

13 A Because I don't know if there is any  
14 reviewing that goes on for the prescriptions that  
15 are -- I don't -- I'm not -- as I mentioned to you,  
16 I'm retired. I don't know what the state of the art  
17 is right now, and I don't --

18 Q When you were there, did Janssen review any  
19 prescriptions to determine whether they were  
20 appropriate or inappropriate?

21 A I don't know. That was not work that was  
22 done by me and my department. So, I don't know the  
23 answer.

24 Q While you were at Janssen, Janssen made  
25 money on all the prescriptions, not just those that

1 were appropriate, correct?

2 MR. LIFLAND: Object to the form of the  
3 question.

4 A I don't know. I don't, I don't know. It  
5 was not an area that I saw. I didn't see that type  
6 of data; so, I don't, I don't know.

7 Q What presents a better long-term business  
8 opportunity for Janssen, use of opioids for acute  
9 post-operative pain or chronic opioid therapy?

10 MR. LIFLAND: Object to the form of the  
11 question.

12 A I think one would have to look at usage  
13 patterns.

14 So, acute pain is something that -- there  
15 is a lot of acute pain. People may use medications  
16 appropriate -- certainly for the treatment of that  
17 pain. There is also a lot of chronic pain, and I  
18 think medications are used as appropriately.

19 I haven't seen a side-by-side comparison of  
20 the dollar amounts that would be generated from an  
21 acute pain market and a chronic pain market. If I  
22 saw that, it was many years ago, and it was  
23 certainly not in something that I regularly  
24 addressed or was not part of my responsibilities at  
25 Janssen.

1           So, I don't know the answer to your  
2 question.

3           Q     Are you aware of the fact that cigarettes  
4 are a profitable product because they are addictive?

5           MR. LIFLAND: Object to the form of the  
6 question.

7           A     I'm aware of the fact that cigarettes are  
8 profitable products. I don't know if that's  
9 necessarily only because they're addictive. I don't  
10 know.

11          Q     Well, companies like repeat business,  
12 correct?

13          A     Companies like recreate -- repeat business,  
14 but good business is to make sure that people are  
15 well cared for and that they're doing well.

16          Q     Have you studied the prior opioid crises in  
17 this country?

18          MR. LIFLAND: Object to the form of the  
19 question.

20          A     I've not -- could you explain that a little  
21 more for me?

22          Q     Yeah.

23                 Were you aware that this is not the first  
24 opioid crisis in this country?

25          A     I'm aware that there may have been, many

1 years ago, a crisis with, I believe, opium and some  
2 of the other ones.

3 I don't know if that's the one you're  
4 referring to or not.

5 Q Are you aware there have been other  
6 medicinal opioid crises in this country?

7 A Not that I'm specifically aware of, no.

8 I was aware of maybe -- I had heard of  
9 illegal opioid, opioid medicines, but not of a  
10 medicinal opioid crisis, another one.

11 Q You've never studied humanity's past  
12 experience with medicinal opioids?

13 A Not in a structured way. No. I mean, I  
14 may have walked through a museum where some  
15 information was available, but I haven't sat down  
16 personally and gone through this.

17 Q Opium-based products have been around for  
18 millennia, correct?

19 A Yes, that's correct.

20 Q And you've never looked into how opium has  
21 been used in the past?

22 A Right. So, what I had testified was, I  
23 heard about the opium dens that we had talked about,  
24 but I don't know specifically as how it may have  
25 been abused as a medicinal product, to your

1 question. No, I'm not familiar with that.

2 Q That's not something you looked into in  
3 your role at Janssen?

4 A I did not.

5 MR. LIFLAND: Are you okay? Do you need a  
6 break?

7 THE WITNESS: A break would be good.

8 MR. DUCK: Okay, let's take a break.

9 THE WITNESS: Thank you.

10 THE VIDEOGRAPHER: Off, 11:13.

11 (Recess taken.)

12 THE VIDEOGRAPHER: Back on, 11:31.

13 Q Do opioids produce euphoria for some  
14 patients?

15 A Yes, they do.

16 Q Do opioids make some patients feel good?

17 A They can.

18 Q Is that the same thing?

19 A I think people use "euphoria" and "feel  
20 good" in the same way.

21 Q And does Janssen use them the same way?

22 A "Feel good" is, is one of the terms that  
23 they use to describe euphoria. So, yes.

24 Q Is that a good thing or a bad thing, for an  
25 opioid to produce euphoria?

1 MR. LIFLAND: Object to the form of the  
2 question.

3 A I think the primary goal, as we know, is to  
4 reduce pain and to get people comfortable. So,  
5 euphoria is not a necessary -- a desirable effect;  
6 so, it's not the primary focus on it.

7 Q Is feeling good a desirable effect?

8 A Feeling good is something that -- it's --  
9 if people are feeling good, that's a good thing, but  
10 that's not the primary intent of using the  
11 medication.

12 Q How does Janssen find out if patients are  
13 experiencing euphoria?

14 A So, we find we learn about euphoria in the  
15 same way we would learn about any adverse event.  
16 Either healthcare providers or patients would either  
17 call in to our information center or fill out a med  
18 watch form, which is a governmental form talking  
19 about that. And so, that would be ways that we  
20 would hear about it.

21 Sometimes, if there were scientific  
22 meetings, when -- we'd check in with people who were  
23 caring for patients who were receiving our  
24 medications, we might find out from them and  
25 which -- and they may -- and we would encourage them

1 to fill out a med watch form, as well; so, we could  
2 capture it formally.

3 Q Did Janssen receive any input directly from  
4 patients about euphoria or feeling good?

5 A So, my experience, what I had heard, was  
6 indirectly, but it relates to patients. I don't  
7 know if you'd want to hear that or not, Counselor.

8 Q Sure.

9 A All right. So, early on, when tapentadol  
10 was first introduced into the U.S. marketplace, we  
11 became aware that there were some reports of  
12 patients noting that -- it's actually almost the  
13 reverse of what you're asking me. So, patients were  
14 taking the medication, and they were describing as  
15 not getting the buzz, not getting the euphoria. And  
16 so, they had interpreted that as indicating that  
17 the, that the drug was not working.

18 I had reached out to the individuals in the  
19 field and said, "Do you know whether the healthcare  
20 providers had actually done an assessment of pain  
21 control or reduction in pain?"

22 And they went back, and, as it turned out,  
23 they did.

24 So, for example, if a patient had a pain  
25 level of level eight, and they did an -- they did



1 a -- asked the patient what the level of pain was  
2 after they started the medication, and had it  
3 dropped from eight to six, then, assuming no other  
4 side effects, that that would be a successful  
5 treatment for that patient.

6 So, we came to understand, at least early  
7 on in the U.S. marketplace, that, in fact,  
8 tapentadol wasn't giving the type of euphoria that  
9 patients may have been -- experienced with drugs  
10 like hydrocodone or oxycodone.

11 So, we were -- in answer to your question,  
12 we are aware of euphoria, we did get that feedback.  
13 But in this case, it was not euphoria, it was  
14 absence of euphoria that we've heard about.

15 But it gets anecdotal. So, I want to make  
16 sure that's clear.

17 Q You also received -- Janssen also received  
18 reports about patients experiencing euphoria with  
19 its drugs?

20 A Yes.

21 Q And patients saying they felt good on the  
22 drug; it made them feel good, right?

23 A Presumably "feel good" would have been a  
24 term -- one of the terms that people might use.

25 "Feel good" and other descriptions would

1 fold into terms called -- of euphoria. So, that  
2 could be.

3 Q Did Janssen ever try to separate them out?

4 A I'm not sure I'm following your question.

5 Q Well, if the term "feel good" got lumped in  
6 with euphoria --

7 A Oh, yes.

8 Q -- did Janssen ever try to tease those two  
9 apart?

10 A So, they would see who came -- what the  
11 reports were for feel good and euphoria, but when  
12 those -- that type of information is submitted to a  
13 regulatory authority, for example, those terms may  
14 fold into the term of "euphoria."

15 Q Did Janssen ever try to do anything that  
16 would prevent the term "feel good" from folding into  
17 "euphoria"?

18 A I don't know how the data were reported  
19 out. I don't know if they were -- sometimes reports  
20 may be the verbatim term and the preferred term.

21 So, the verbatim term, to your point, would  
22 be "feel good," and the preferred term would be  
23 "euphoria." And they may have, in fact, provided  
24 that information for both terms. So, they may have.

25 Q You're not sure one way or another, though?

1           A     Not -- it's not certain. I think we did  
2     try and include the verbatim terms, but I can't  
3     testify to that. I'm not sure.

4           Q     Exhibit 6.

5                     (JAN-MS-00491920 was marked as  
6                     Vorsanger 6 for identification,  
7                     as of this date.)

8           Q     Okay. This Exhibit 6 is a medical  
9     development project statement, right?

10          A     Yes.

11          Q     Showing the status as of June 26, 2001,  
12     correct?

13          A     Yes.

14          Q     And this document, the format it's in, it's  
15     a format that was commonly used by Janssen?

16          A     It was a doc -- it was a format that was  
17     used at that time. I don't know that that format  
18     was preserved and used going after that time.

19          Q     Sure. But you recognize the format of this  
20     document?

21          A     At this time, yes.

22          Q     Okay. What does this document reflect?

23          A     This is a document that was designed to  
24     identify the nature of the data that would be of  
25     interest to people and then to -- and to kind of set

1 out a dissemination strategy for the data.

2 So, it's -- do you want me to go through  
3 the document with you?

4 Q Yes.

5 A Oh, sure. All right.

6 Q Please.

7 A So, the outcome statement, submission of  
8 one or more abstracts to one or more major  
9 meetings -- and this is identified as the American  
10 Pain Society in '04.

11 So, the thinking would be that the study  
12 would have been completed by, you know, let's say  
13 six months earlier, or a period of time that they  
14 could submit it.

15 Q So, let me stop you there.

16 At this point in time, the study had not  
17 been completed?

18 A I don't even know if the study was  
19 initiated at this point.

20 Q Okay.

21 A This may have been a draft document with  
22 the intent of how the data might be used for this  
23 study.

24 Q This is a plan for a study that will be  
25 conducted in the future?

1 A I think it was a draft plan.

2 Q Okay. Thank you.

3 Please continue.

4 A Okay. I'm sorry, Counselor, do you have  
5 any other questions now?

6 Q No. Please continue.

7 A Okay. So, we talked about when the data  
8 would be available.

9 One quarter after the 12.5-micrograms,  
10 which we call the 12 patch, of which would be -- the  
11 projected launch date was the fourth quarter of  
12 2003. And it talks about the study calls for the  
13 clinical trial of approximately \$6 million.

14 I'm not sure what "CT costs" means, at this  
15 point.

16 Q Okay. A couple of questions about that.

17 A Sure.

18 Q So, this plan shows that the launch of the  
19 study would start in the fourth quarter of 2003 --

20 A Let me see.

21 Q -- or a certain patch?

22 A No, I think this was -- the data will be  
23 available by one quarter after the 12-microgram  
24 patch launches. So, there was another formulation.

25 And I think the thinking at that time was

1 that that launch would -- this is my interpretation  
2 of the document -- that the launch date for the  
3 patch would be the fourth quarter of 2003.

4 Q Okay. And this study in -- regarding  
5 Duragesic --

6 Which is the patch, right?

7 A Yes.

8 Q -- is meant to accompany or follow behind  
9 the launch of a new patch, right?

10 A That's what it looks like.

11 Q Okay. And then below -- and by the way,  
12 the medical director listed on this document is you?

13 A That's correct.

14 Q Then you'll see there's strategic linkage.

15 Do you see that?

16 A Yes.

17 Q And it says, "This trial is linked to two  
18 strategies."

19 Can you please read those two strategies?

20 A Yes.

21 "Expand Duragesic use in the nonmalignant  
22 pain market while differentiating from the  
23 competition."

24 And two, "Maximize cost and reimbursement  
25 opportunities."

1 Q Thank you.

2 This goes on to talk about what the study  
3 may conclude or result in; is that right?

4 A I think the trial should demonstrate -- and  
5 again, this is what -- this is aspirational. We  
6 would hope -- we don't know what the data are going  
7 to show. We have to do the study.

8 "But the trial should demonstrate the  
9 improvement in pain scores, as well an improvement  
10 in activities of daily living" -- which we define as  
11 "ADL" -- "over prior treatment."

12 And I don't have a draft protocol. I don't  
13 know what the study population is, other than to say  
14 it's individuals with low back pain. So, we -- I  
15 don't have that data in front of me now to comment.

16 "ADLs will be measured -- events of daily  
17 living will be measured using a validated  
18 instrument, such as the Oswestry Disability Index.  
19 This trial will provide data to advise clinicians on  
20 how to use 12.5 mcg patch and will advise our  
21 strategic customers (HMO, PPMs) the quality of life  
22 benefits of the patch usage for pain while  
23 improvement in patients with chronic low back pain."

24 Q Thank you.

25 And then below this, we see a chart that

1 shows "Key Milestones."

2 A Yes.

3 Q It shows "Risks and Competitive Threats,"  
4 right?

5 A Yes.

6 Q It shows "Financials," yes?

7 A Yes.

8 Q And "Issues," right?

9 A Yes.

10 Q And let's look at the "Risk and Competitive  
11 Threats."

12 Do you see the first bullet point there?

13 A Yes.

14 Q Can you please read that?

15 A Yes.

16 "Small risk of NS," which I'm interpreting  
17 mean "nonsignificant" -- "improvement in quality of  
18 life and functionality measures."

19 What that means is, when this was put  
20 together, we believed strongly that the patch would  
21 be effective; and we believe that, as patients felt  
22 better and their pain was better controlled, then  
23 the events of daily living might be reflected in  
24 that.

25 And we believed that, again, the risk could



1 be small, but this is what we had said.

2 Q The risk would be small that the study  
3 would not show what Janssen expected it to show?

4 A The -- yes.

5 Q Thank you.

6 Do you know whether or not this study was  
7 ever conducted?

8 A I don't think this study ever came to  
9 fruition, but I don't know. I don't recall.

10 Q Can you please read the second bullet point  
11 under "Risk and Competitive Threats"?

12 A Yes.

13 "Pain control is not significantly  
14 different than prior treatment.

15 Q Okay. And that means that the study may  
16 show that the pain relief that the patient received  
17 with the Duragesic patch was not significantly  
18 better than what other prior treatment they  
19 received, right?

20 A That's what that means.

21 But, but it's important to understand that  
22 if these patients are going on a patch, that they  
23 may have been on other opioid analgesics and their  
24 pain control may be good, and so that that pain  
25 control may continue on the patch. But if you look

1 at differences between the before and after, they  
2 may not be dramatically different.

3 Q The --

4 A The study design usually is set up to see  
5 that we're able to provide analgesia to patients  
6 going into the study. They usually have to have a  
7 fairly significant amount of pain even to come into  
8 the study.

9 So, typically, patients would be people, if  
10 you look at the study design, who have inadequate  
11 pain control.

12 But this was identified as a potential  
13 issue.

14 Q Are you familiar with a program called  
15 MeDRA, M-E-D-R-A?

16 A I remember the term, but I don't remember  
17 the context.

18 Q All right. I'm going to hand you what's  
19 marked as Exhibit 7.

20 (JAN-MS-00605509 through 510 was  
21 marked as Vorsanger 7 for  
22 identification, as of this  
23 date.)

24 Q All right. If you'll turn to the second  
25 page, this is an email from you to several people at

1 Johnson & Johnson companies, right?

2 A I'm sorry, Counselor, the second page is  
3 one that I wrote to Jim Xiang.

4 Is that the one you're referring to?

5 Q That's the one I'm referring to.

6 And there are additional J&J employees  
7 copied, right?

8 A Oh, I see. I'm sorry, I was on the  
9 previous page.

10 Q No problem.

11 A Yes, yes, that's right.

12 Q And then the subject line of your email is,  
13 "Euphoria versus feeling good."

14 A Yes.

15 Q Right?

16 A Yes.

17 Q And you state, in the second sentence here,  
18 "Jim, we are interested in understanding whether  
19 there may have been a difference in perceived mood  
20 changes for subjects in the Nucynta ER clinical  
21 trials that were treated with either Nucynta ER or  
22 oxycodone CR."

23 Right?

24 A Yes.

25 Q Can you please read the next paragraph for

1 me.

2 A "So, for example, some subjects may feel --  
3 have reported euphoria (an adverse event with a  
4 negative connotation) and others may report 'feeling  
5 good' (a positive effect)."

6 Q Thank you.

7 Then in the last paragraph, you'll see  
8 reference to MeDRA.

9 Do you see that?

10 A Yes.

11 Q And you write, "One obvious challenge is  
12 that MeDRA may promote the verbatim term of 'feeling  
13 good' to the preferred term of 'euphoria,' which  
14 would be a problem, because then one cannot separate  
15 the terms."

16 Did I read that right?

17 A Yes.

18 Q What is MeDRA?

19 A So, MeDRA is, I believe, a medical  
20 dictionary that talks about various adverse events.

21 And this reflects what I had said earlier  
22 in my testimony, that the terms may come in as  
23 "feeling good," and, as we had indicated, as  
24 something that could be a good thing.

25 And you may be elevated -- or I use the

1 word "promoted to," which is sometimes the way it's  
2 used -- to euphoria -- to the word "euphoria."

3 So, we were -- and what I had commented on,  
4 as you can see, is I had reached out to a  
5 psychiatrist, because I wanted to understand what  
6 the differences were between those.

7 So, I reached out to one of my psychiatry  
8 colleagues, and he helped explained that it's an  
9 important thing from psychiatrists, because  
10 apparently feeling good can be distinguished from  
11 euphoria.

12 So, part of the analysis was to really  
13 understand -- even though medically we may lump  
14 these together or, as I say, promote one to the  
15 other, there may be reasons where we really want to  
16 understand, to your point, how do we drill down and  
17 look at euphoria, et cetera.

18 So, that was why we actually did look at  
19 this.

20 Q You didn't want feeling good -- the term  
21 "feeling good" to get lumped in with "euphoria"?

22 A No, I wouldn't say that. I would -- I --  
23 we wanted to make sure that we understood the  
24 differences between the two.

25 Q You say "because then one cannot separate

1 the terms."

2 You wanted them to be separate, right?

3 A Right, because of the reasons I just  
4 testified to, was that the psychiatrists had  
5 indicated that those might be important differences.

6 Q Well -- and, as you state at the very  
7 beginning, euphoria is an adverse event with  
8 negative connotations, right? That's what you say.

9 A Yes, I do.

10 Q And you say, also, that feeling good is a  
11 positive effect?

12 A Actually what I say is, and others may  
13 report feeling good as a positive effect.

14 But they would still all be reported as  
15 adverse events. And that's important.

16 Q Let's be, let's be clear.

17 The positive effect is in quotations as  
18 your comment, right?

19 A Correct. But it's still an adverse event,  
20 because it's all folded into the adverse event of  
21 euphoria. That's the point of this discussion.

22 Q And it was all reported to the FDA?

23 A Yes.

24 Q And the FDA would see a report of feeling  
25 good as a negative effect?

1           A     Yes, because all of these are reported as  
2     adverse events.

3                 So, there are positive effects from adverse  
4     events that are still adverse events.

5                 For the drug minoxidil, for example, for  
6     hair loss, was a -- is that some people perceived as  
7     a positive effect. But when the drug was first  
8     introduced into the market, a hair gain I'm -- I'm  
9     growing it for hair gain was an adverse event. It  
10    was an adverse event that people went out and  
11    promoted to -- for hair, for hair regrowth.

12                So, there are some adverse events that may  
13    have a positive spin, but they're still adverse  
14    events.

15                So, feeling good would have been reported  
16    as euphoria as an adverse event.

17            Q     It would have been appropriate for feeling  
18    good to be reported as an adverse event --

19            A     Yes --

20            Q     -- not --

21            A     -- even though -- well, people may think  
22    it's a positive effect, but it's an adverse event.

23            Q     And you wanted people to be able to  
24    separate those, right?

25            A     Well, we would never have promoted on it,

1 anyway, and talked about it. The analysis that we  
2 talked about -- and I provided the reasons for why  
3 we did that -- are here.

4 Q It would have been inappropriate to promote  
5 on this issue, correct?

6 A We would not have promoted on it.

7 Q Because it would have been inappropriate?

8 A We would not promote on it because it was  
9 not -- it was, it was not part -- it was only a  
10 single adverse event. So, we did not promote on  
11 that.

12 Q It would have been inappropriate to promote  
13 on the difference between euphoria and feeling good,  
14 correct?

15 A Yes, that's correct.

16 Q Who is Dr. Russell Portenoy?

17 A Dr. Russell Portenoy is a pain specialist.

18 Q When is the last time you spoke to him?

19 A Quite a while ago.

20 Q He was a friend of yours, correct?

21 A He was a colleague of mine. I wouldn't say  
22 that he was a friend of mine.

23 Q But you knew him personally?

24 A I knew him personally.

25 Q And you worked with him?



1           A     I, I -- he provided consultation to the  
2     company. And in that way, that's how I met him.  
3     But I did not know him socially, and I did not go  
4     out with him socially.

5                     That's how I would define a friendship.

6           Q     Janssen used Dr. Russell Portenoy as a KOL,  
7     right?

8           A     Yes.

9                     MR. LIFLAND: Object to the form of the  
10    question.

11          Q     And what is a KOL?

12          A     A key opinion leader.

13          Q     Janssen used many different key opinion  
14    leaders for its opioid analgesics, right?

15                     MR. LIFLAND: Object to the form of the  
16    question.

17          A     I don't know whether I would use the word  
18    "many."

19          Q     How many?

20          A     I don't know.

21          Q     More than 10?

22          A     I don't know what the number would be, but  
23    we -- Janssen used a number of individuals who are  
24    key opinion leaders in the work, in their work.

25          Q     More than 100?

1 A No, sir, I don't believe it was that many.

2 Q How big was the speakers' bureau?

3 A The speakers' bureau, I don't know how big  
4 it was in its day. That would be a question that  
5 the marketing group would be able to answer, not at  
6 the medical group, whether all the speakers were  
7 considered key opinion leaders or whether they were  
8 just knowledgeable clinicians, and one could, could  
9 make a distinction between those two.

10 Q How are key opinion leaders identified?

11 A I'm not sure if there's a formal process  
12 that's used. But one of the -- some of the things  
13 we think about is the number of publications they  
14 have and that type of thing.

15 So, if I were a knowledgeable clinician,  
16 for example, where I was knowledgeable about the use  
17 of our products, that individual, she or he, may go  
18 out and speak at a speakers' bureau.

19 If I were a key opinion leader, I would be,  
20 typically, someone who has published a lot, maybe  
21 sat on FDA advisory boards and has distinguished  
22 himself academically and through publications and  
23 research.

24 Q Someone who is credible, right?

25 A Well, I think -- I mean, I think the

1 clinicians are very credible, because they have  
2 experience caring for the patients, as well.

3 So, I think the criteria that I provided,  
4 Counselor, in my testimony is a way that I think  
5 about distinguishing KOLs from other knowledgeable  
6 individuals.

7 Q And one of the reasons you want to have a  
8 distinguished KOL is because they are more  
9 influential that way, right?

10 MR. LIFLAND: Object to the form of the  
11 question.

12 A We -- the individuals that one would want  
13 to work with would be some of the more most  
14 knowledgeable people that we have, not only about  
15 our other -- own compound, but other compounds or  
16 type of thinking that's going on in the field: What  
17 are people thinking about for the next set of drugs  
18 in development? What are the important issues that  
19 are going on in analgesia?

20 Q Is it your testimony that Janssen did not  
21 consider whether a KOL would be influential to his  
22 or her audience?

23 A I think we understood the fact that people  
24 who were -- people who published a lot and people  
25 who were respected in the field would be important,

1 and people who actually had used our medications and  
2 understood how to use those medications would be the  
3 people that we felt would be important, and I would  
4 want to listen to; that they, frankly, knew what  
5 they were talking about.

6 Q Because -- the reason Janssen would want to  
7 use those types of individuals you just described is  
8 they are influential?

9 MR. LIFLAND: Object to the form of the  
10 question.

11 A They may be influential, but I think that  
12 people listening to that will form their own  
13 opinions in terms of their own clinical experience.

14 Q Well, that's not my question.

15 My question is this:

16 A reason that Janssen selects certain KOLs  
17 is that they are influential?

18 MR. LIFLAND: Object to the form of the  
19 question.

20 A I don't know what the criteria Janssen used  
21 to select who the KOLs are.

22 When I look to see people who I might want  
23 to work with, the criteria that I had already  
24 testified was important for me to identify those  
25 individuals.

1 I don't know that the company identified  
2 formal criteria.

3 Q You don't know that?

4 A No, sir, I don't.

5 Q You've never seen anything about that?

6 A I don't recall a list specifically.

7 Whether there were criteria at the company, I don't  
8 know.

9 Q Would it have been inappropriate for  
10 Janssen to rank KOLs based on their ability to  
11 influence their audience?

12 MR. LIFLAND: Object to the form of the  
13 question.

14 A I would need to understand the  
15 circumstances better to be able to do that.

16 Q What don't you understand about my  
17 question? I would like to clarify it for you.

18 A Sure. I think, if one were going to do a  
19 ranking of KOLs, it may depend on where those  
20 individuals could be -- in what settings those could  
21 be used.

22 So, for example, somebody who had  
23 national -- someone who was nationally recognized in  
24 something might be appropriate for situations in  
25 where a national, a national audience would be more

1 desirable.

2           Somebody may be a regional KOL, would have  
3 more people in the area where they worked at. It  
4 could be in the south, it could be in the far west,  
5 et cetera. In those types of interest, that would  
6 be a more appropriate setting.

7           So, it may be that, as the company  
8 identified a list of key opinion leaders, it may  
9 have been to stratify to see where it would be most  
10 appropriate to have those people work with the  
11 company or represent the company.

12       Q     The marketing department helped to identify  
13 KOLs that Janssen would use, right?

14       A     So, there are a number of KOLs -- recall  
15 that I had started at Janssen in 2000 -- I'm going  
16 to answer your question.

17       Q     Yeah, if you will answer the question yes  
18 or no, and then you're welcome to --

19       A     Okay. So, I think the marketing department  
20 did have an involvement on it.

21           But I want to qualify that, that the  
22 activities that would have gone on in identifying  
23 some of the KOLs that were already at the company  
24 when I got there would have had a period of  
25 approximately 10 years.

1           So, when those people -- when I joined  
2           Janssen in 2000, there were people who were already  
3           KOLs. And I don't know what criteria or who  
4           selected those criteria for those people.

5           Q     You don't know one way or another?

6           A     Correct.

7           Q     All right. For those that were selected  
8           while you were there, the marketing department was  
9           involved in their selection, correct?

10          A     The marketing department may have been  
11          involved in certain selection, but those -- yes.

12                 So, to qualify, those may be related to  
13          marketing-related activities that were appropriate  
14          and, again, as deemed appropriate in terms of how  
15          they would work with the company.

16          Q     Key opinion leaders that Janssen hired were  
17          used to promote Janssen products, right?

18                 MR. LIFLAND: Object to the form of the  
19          question.

20          A     Key opinion leaders were used in  
21          company-sponsored settings using approved materials  
22          to discuss Janssen products.

23          Q     And promote them?

24          A     To identify them as products that certainly  
25          could be used for patients, for appropriate

1 patients.

2 Q So, that prescribers would understand how  
3 to use Janssen's products, right?

4 A They could understand how to effectively  
5 use those products.

6 Q When to use them, right?

7 A That would be a -- that would be a decision  
8 by the prescriber, but we would be providing  
9 additional information to them.

10 Q And Janssen's hope is that that would lead  
11 to additional prescriptions of Janssen's products?

12 A As deemed appropriate. I think we wanted  
13 to inform, to make sure that people -- that  
14 prescribers and patients were aware of their  
15 therapeutic options.

16 And then, in instances, certain drugs may  
17 be better or worse than other ones. And that would  
18 be a decision that the clinician would need to make  
19 in counsel, in conjunction with the patient.

20 Q Well, the purpose of Janssen's educational  
21 activities -- the purpose is -- one purpose is to  
22 increase the prescription of Janssen products?

23 A I don't agree with that.

24 Q Okay. And do you agree with the fact that  
25 one reason why Janssen engaged in promotional



1 activity is to increase the prescribing of Janssen's  
2 products?

3 A Promotional activities -- no -- well, in  
4 part. I would have to say in part.

5 I think it was critically important for the  
6 company to understand that the products were using  
7 safe and effectively [sic], as I've testified  
8 earlier today.

9 And part of the promotional activities were  
10 to make sure that people understand safe use of the  
11 product.

12 Q Janssen employed sales reps to promote its  
13 opioid products, correct?

14 A That is correct.

15 Q Janssen employed sales reps to market its  
16 opioid products, correct?

17 A Yes.

18 Q And sales reps -- new question.

19 And what sales reps do is sell?

20 A Yes.

21 Q Thank you.

22 So, I'm going to hand you Exhibit 8.

23 (JAN-MS-00337085 through 086 was  
24 marked as Vorsanger 8 for  
25 identification, as of this

1 date.)

2 Q By the way, I'm just going to ask you about  
3 the first two emails on this page, so...

4 A Okay.

5 Q Who is Johnette Johnson?

6 A I think she is a marketing person, but I'm  
7 not certain.

8 Q And she's asking about Dr. Russell Portenoy  
9 in this email, correct?

10 A Yes.

11 Q She sent an email to Frank Demiro.

12 Who is Frank Demiro?

13 A Frank Demiro is a marketing person.

14 Q And this was in 2013, right?

15 A Yes.

16 Q Johnette Johnson says, "Frank, the KOL for  
17 whom I was trying to seek your counsel and maybe  
18 background information was Russell Portenoy. Any  
19 insights you can provide would be very helpful.  
20 Thanks so much."

21 Did I read that right?

22 A Yes.

23 Q Demiro then responds to Johnette and says,  
24 "Please talk with Gary Vorsanger. He is personal  
25 friends with Russ and can provide you with all the

1 details that you need. He is not a speaker, but is  
2 very influential."

3 Did I read that right?

4 A Yes.

5 Q Do you disagree with anything there?

6 A Well, as I already testified, Dr. Portenoy  
7 and I were colleagues, and not friends. We  
8 certainly knew each other. So, if there was an  
9 interest in identifying from the med -- at Janssen  
10 in medical who knew Dr. Portenoy, I knew him as I've  
11 testified.

12 Q Frank Demiro is a marketing guy, right?

13 A Yes, he is.

14 Q All right. Do you see the last sentence he  
15 wrote here?

16 A "He's not a speaker, but is influential."

17 Q "Very influential"?

18 A "Very influential," that's right.

19 Q Who is he talking about?

20 A Dr. Portenoy.

21 Q Thank you.

22 I hand you what we'll mark as Exhibit 9 to  
23 your deposition.

24 (JAN-MS-02337833 through 835 was  
25 marked as Vorsanger 9 for

1 identification, as of this  
2 date.)

3 Q It's an email chain from 2002, in which  
4 you're copied.

5 A Thank you.  
6 (Perusing document.)

7 Q Are you ready?

8 A Yes, sir.

9 Q Do you remember this email?

10 A In looking it over, I wouldn't say I  
11 remember it. But now that I read it, I'm  
12 familiarizing myself with it.

13 Q Who is Heather Thomson?

14 A Heather Thomson was a medical scientist  
15 liaison at Janssen.

16 Q Do you know whether she's still there?

17 A No, she's not -- I don't believe she is  
18 there. She left a while ago.

19 Q Why did she leave?

20 A To take another job.

21 Q Do you know what year that was?

22 A I don't know. I don't.

23 Q What is a medical science liaison at  
24 Janssen?

25 A So, a medical scientist liaison is

1 typically an individual who may have an advanced  
2 degree, a PharmD or a Ph.D., who would interact in  
3 peer-to-peer communications or discussions with  
4 healthcare providers or key opinion leaders.

5 Q Thank you very much.

6 Let's start on the last page.

7 She sent an email to Bruce Moskovitz,  
8 right? Last page.

9 A The last page is -- yes, from Heather to  
10 Bruce. Yes, I see it.

11 Q Thank you.

12 She says, "Bruce, Clare Harte says, because  
13 of HCC, we can't create information on KOLs that we  
14 wouldn't share with them, which, according to her,  
15 kills the opponent/neutral/advocate categorization."

16 Did I read that sentence right?

17 A Yes.

18 Q Who is Clare Harte?

19 A Clare Harte was a project manager who  
20 worked with -- in my group.

21 Q For opioids?

22 A Yes.

23 Q In the medical affairs department?

24 A Correct.

25 Q What is HCC?

1 A Health care compliance.

2 Q That's a department at Janssen?

3 A Yes, it is.

4 Q Do you recall this rule that you could not  
5 create information on KOLs that wouldn't be shared  
6 with them?

7 A I recall that there were conversations in  
8 health care compliance. And there's a reference to  
9 one of our attorneys, as well, indicated that this  
10 type of categorization, if the company was going to  
11 do it, would need to share it with them, which is  
12 what it says here.

13 Q Okay. And Heather Thomson references "the  
14 opponent/neutral/advocate categorization of KOLs,"  
15 correct?

16 A That's what it says.

17 Q And that means that, at one point in time,  
18 Janssen placed different KOLs in one of those three  
19 categories?

20 MR. LIFLAND: Object to the form of the  
21 question.

22 A I think, at one time, Janssen was trying to  
23 understand whether there may be a way or not to  
24 begin to look at KOLs. I described the  
25 stratification earlier in my testimony. There may

1 be another way of thinking about it -- this way, as  
2 well, as it says in the email. I don't think any of  
3 this actually came to pass.

4 Q It goes on to say, "She thinks we have to  
5 stick to only capturing stuff like research projects  
6 funded, speaking engagements, and other snooze  
7 data."

8 What is "snooze data"?

9 A I don't know what she means by that.

10 Q She means boring data, right?

11 A I would -- I think that's a good  
12 assumption.

13 Q "I am backing off further development of  
14 this idea until we get the ground rules straight."

15 Right?

16 A Yes.

17 Q What -- did Janssen ever get the ground  
18 rules straight?

19 A Yes. We did not do this type -- I don't  
20 believe we ever -- we moved forward with  
21 categorizing the KOLs in this manner.

22 Q In what manner did Janssen categorize the  
23 KOLs?

24 A I think these were individuals who were  
25 brought to work at the company based on some of the

1 criteria I've already testified, in terms of their  
2 publications, et cetera, rather than this type of  
3 categorization, as Heather has identified in her  
4 email.

5 Q Is it your testimony that Janssen never  
6 placed KOLs into named categories?

7 A My testimony is that I don't recall that  
8 type of information.

9 Q Fair enough.

10 So, Bruce Moskovitz responds to this,  
11 right?

12 A You're looking at the email on the page  
13 before, Counselor?

14 Q Pardon me. I may not be.

15 Yes.

16 A Okay. I'd like to -- should I read it?

17 Okay.

18 (Perusing document.)

19 Okay.

20 Q So, Bruce Moskovitz responds to Heather  
21 Thomson's email, right? Bottom of the page.

22 A Yes. So, Heather wrote an email to Michele  
23 Cole and Bruce on the bottom of the first page --

24 Q I'm looking at the bottom of the second  
25 page.



1           A     Right.  So, your -- I think your comment to  
2     me -- and if I misunderstood, I apologize -- was  
3     Bruce's email to Heather, yes.

4           Q     Thank you.

5                     So, Bruce Moskovitz is responding to the  
6     email from Heather that we just read about  
7     information on KOLs, right?

8           A     I'm confused in the sequence, and I  
9     apologize for that.  Heather's email looks like it  
10    came after Bruce's email, if I got this right.

11                    So, Heather wrote an email to Bruce saying,  
12    "We're not able to move ahead."

13                    The email before that was Bruce reaching  
14    out to the other -- Heather and the other KOLs,  
15    saying, "Listen, we need to really understand this  
16    better."

17                    So, maybe I don't have the sequence right.  
18    And if I don't, I apologize.  It looks like this  
19    email (indicating) -- okay.  It was a few minutes  
20    apart.  I see.

21                    So, yes.  So, Heather's email was on the  
22    22nd to Bruce, and this is Bruce's email.  Yes, sir.  
23    Okay, I got it straight now.

24           Q     All right.  So, we're on the same page.

25           A     Sorry.  Yup.

1 Q Heather Thomson sent an email to Bruce  
2 Moskovitz --

3 A Two days later, right.

4 Q Two days later, Bruce Moskovitz responds to  
5 Heather Thomson?

6 A Yes, two days later.

7 Q Okay. And I'm looking at that email from  
8 Bruce Moskovitz.

9 A Right.

10 Q Bruce says, in response to Heather's email,  
11 "Obviously not something we can proceed with  
12 lightly. This will take discussion directly among  
13 us and perhaps at the RMAC."

14 Did I read that correctly?

15 A Yes.

16 Q What is the RMAC?

17 A I don't remember.

18 Q Bruce goes on to say, "But I think there is  
19 a way to do it. We just need to find out how."

20 Correct?

21 A That's what it says.

22 Q And the "it" he's referring to is  
23 categorizing KOLs, correct?

24 A Yes.

25 Q He goes on to say, "Brand team collects

1 lots of information on our docs. In this case, it  
2 isn't even information we're collecting, just a  
3 reasoned assessment based on those data."

4 Right?

5 A Yes.

6 Q Okay. Above that email, Michele Cole  
7 responds.

8 A Yes.

9 Q A day later, correct?

10 A Yes.

11 Q Who is Michele Cole?

12 A She is another medical scientist liaison.

13 Q She is someone who, like Heather Thomson,  
14 would communicate with prescribers and KOLs?

15 A Yes, mostly KOLs, but with some --  
16 certainly would be able to discuss things with  
17 prescribers.

18 Q And that would involve discussions about  
19 Janssen's products, in some instances?

20 A Yes.

21 Q Thank you.

22 You'll see that Michele Cole weighs in on  
23 this issue and uses Dr. Russell Portenoy as an  
24 example, correct?

25 A Yes.

1 Q She describes Dr. Russell Portenoy as "a  
2 frequent author of publications," correct?

3 A Yes.

4 Q "Editor or reviewer of The Pain Journal,"  
5 right?

6 A Right.

7 Q "A current or past officer of APS and  
8 AAPM," right?

9 A Yes.

10 Q What is APS?

11 A American Pain Society.

12 Q What is AAPM?

13 A It's either the American Academy of Pain  
14 Management or American Academy of Pain Medicine.  
15 They both had the same initials.

16 Q He was also on a guideline development or  
17 task force, right?

18 A Yes.

19 Q And "influential, as perceived by peers,"  
20 correct?

21 A Correct.

22 Q Did you ever share this information with  
23 Dr. Russell Portenoy?

24 A I did not, personally.

25 Q Why not?

1           A     Because these are activities that went on  
2     with the medical scientist liaison group, which was  
3     separate from the work that I had done with them.

4           Q     So, do you respect Dr. Russell Portenoy?

5           A     I do.

6           Q     As a scientist?

7           A     Yes, I do.

8           Q     As a physician?

9           A     Yes.

10          Q     And as an expert on issues around the  
11     treatment of pain with opioids?

12          A     Certainly when I worked with him, yes.

13          Q     So, Heather Thomson responds to Michele  
14     Cole. You'll see the third sentence. She's talking  
15     about Michele's email. She says, "This is a great  
16     way to determine whether a person is influential.  
17     And we might, in fact, be able to assist that  
18     practitioner in becoming more influential."

19                 Did I read that sentence right?

20          A     Yeah, I'm sorry, Counselor, I -- I've got  
21     the one that says, "It strikes me we've got two  
22     different types of categorization going on."

23                 Is that --

24          Q     Yeah.

25          A     Okay. That's the one you're looking at.

1           Q     The third sentence there says, "This is a  
2     great way to determine whether a person is  
3     influential, and we might, in fact, be able to  
4     assist that practitioner in becoming more  
5     influential."

6                     Did I read that sentence correctly?

7           A     Yes, you did.

8           Q     The email chain continues, and Michele  
9     Cole -- well, let me -- before we move on, Heather  
10    Thomson's email goes on to say, "However, if the  
11    person is clueless about opioids and has no  
12    knowledge of Duragesic, then I really don't want  
13    them to become more influential."

14                     Correct?

15          A     Yes.

16          Q     All right. Michele Cole responds to this  
17    email, and she says, "Well said. I guess I missed  
18    the most relevant point, that the KOL needs to be  
19    well-versed regarding the use of opioids. I guess I  
20    assumed this, but did not state it. We will only  
21    call on KOLs that are opioid users. We don't want  
22    to serve meat to a vegetarian."

23                     Did I read that paragraph right?

24          A     You did.

25          Q     Heather Thomson responds to this email.

1           And I would like for you to read this  
2 email, but sometimes you read a little quickly, and  
3 I'd ask you, if you wouldn't mind, to slow down --

4           A     Sure.

5           Q     -- a little bit. Thank you.

6           A     Okay.

7           MR. LIFLAND: Maybe you can read it  
8 yourself.

9           MR. DUCK: That's okay. I've --

10          MR. LIFLAND: It's not his email. You're  
11 asking him to read something he didn't write  
12 into the record.

13          Q     Sir, would you mind reading this email out  
14 loud into the record?

15          A     Okay. And the qualifications have already  
16 been made that I did not write the email.

17                But the email says, "No, I want to seduce  
18 the vegetarians with a thick, juicy steak. If I  
19 have to jump on -- jump -- if I have to start them  
20 on limp tuna salad and work them up through some  
21 stupid pasta dish with pieces of chicken, that's  
22 okay. I think we want both/and: Help them become  
23 more effective in their capacity as thought leaders  
24 and help them increase their expertise in the area  
25 of systemic opioid therapy."

1 Q Thank you, sir, for reading that.

2 And what was your response to Heather's  
3 email?

4 A The policy is about how --

5 Q Sir, I'm asking you, on this page --

6 A Yes.

7 Q -- what was your response to this email?

8 A I didn't comment on any emails.

9 Q Do you see the very first email on this  
10 page?

11 A Yes. My general -- oh, sorry, I did not  
12 see my one at the top.

13 "A gentle word of caution: Please see Mike  
14 Chester's admonitions on email."

15 Q Okay. Heather Thomson shouldn't have  
16 written what she wrote in this email, should she?

17 A I think an email like this would require a  
18 lot of explanation, rather than put it in one such  
19 as it is.

20 Q Who is Mike Chester?

21 A He is somebody from the J&J legal  
22 department.

23 Q What was his admonition?

24 A That --

25 MR. LIFLAND: Objection. Instructed not to



1 answer. This is attorney-client privilege.

2 MR. DUCK: It's been disclosed in this  
3 email that you gave us --

4 MR. LIFLAND: The fact that advice was  
5 given was disclosed. The content of the advice  
6 was not disclosed. It's privileged. I've  
7 instructed the witness not to answer.

8 Q Do you recall the admonition?

9 A I do not.

10 Q You just know it related to email?

11 A Yes, from what I've written here.

12 Q Was Dr. Portenoy a vegetarian or a  
13 carnivore?

14 A I don't know.

15 Q Did you tell him which one he was?

16 MR. LIFLAND: Object to the form of the  
17 question.

18 A I'm sorry, Counselor, I didn't hear your  
19 question.

20 Q Did you tell him whether he was a  
21 vegetarian or a carnivore?

22 A No, sir, I did not.

23 Q Did you share this information from Heather  
24 Thomson with the KOLs, in accordance with the policy  
25 of sharing information about them?

1 A I did not.

2 MR. LIFLAND: Object to the form of the  
3 question.

4 A The policy was that with -- if the company  
5 decided to go ahead and do a stratification, that  
6 the content of that information would be shared with  
7 the KOLs.

8 I don't -- I think -- I believe that I  
9 testified that I didn't know how they moved forward,  
10 but I did comment that they -- at some point, they  
11 were thinking about stratifications.

12 So, I don't know what material would have  
13 been shared with the key opinion leaders.

14 Moreover, if that happened, that might have  
15 been activities I would have done with the medical  
16 scientists liaisons, but I -- there was not a group  
17 that I was responsible for. So, I don't know what  
18 happened.

19 Q The medical science liaison group is in the  
20 marketing department?

21 A No, sir, they're not. They're in medical  
22 affairs.

23 Q They're in medical affairs department?

24 A Yes, sir.

25 Q Okay, thank you.

1 I'm handing you Exhibit 10.

2 (JAN-MS-02102667 through 671 was  
3 marked as Vorsanger 10 for  
4 identification, as of this  
5 date.)

6 Q This is a printout from the SCEPTRE --  
7 well, first of all, you told us what SCEPTRE was  
8 earlier.

9 Can you remind me what SCEPTRE is, please?

10 A So, SCEPTRE is the J&J adverse event  
11 reporting system.

12 Q How do adverse events get reported? Is it  
13 directly to J&J?

14 A It can come in through J&J. They can come  
15 in through clinical trials that happen. They can  
16 come in from consumers. They can come in from  
17 healthcare providers.

18 Q This is not RADARS?

19 A So, I don't know what the origin of this  
20 is, but RADARS data would have -- if there were  
21 adverse events identified, would have come in and  
22 been introduced into SCEPTRE.

23 Q Okay. What about DAWN data?

24 A I don't know about DAWN.

25 Q So, SCEPTRE was a program at Janssen that

1 would have included adverse events reported directly  
2 to Janssen and adverse events that were in the  
3 RADARS data?

4 A I believe the RADARS data -- I believe that  
5 the RADARS adverse events were reported to SCEPTRE.  
6 That's what I believe.

7 Q Okay. And this is an adverse event report  
8 for Nucynta, correct?

9 A Yes.

10 Q Do you know what years this is for?

11 A No, I don't. Not clear.

12 Q You'll see the print date at the bottom  
13 right is 2015.

14 Do you have the start date, or can you  
15 point me to it?

16 A I don't see that on the top. I see the AER  
17 number, VER -- which I don't know what "VER"  
18 means -- the queue, the suspected product, the  
19 reaction, the reaction date, seriousness, and if  
20 there was a reporter, that would be listed.

21 But I don't know where these data come  
22 from.

23 Q Are these the low mentions for Nucynta that  
24 you were talking about?

25 A So, one would have to have a conversation a

1 little bit about -- so, I testified that I don't  
2 know where these data come from.

3 One would also need to understand how AEs  
4 are reported. So, if someone has an AE and it  
5 continues or gets worse, that may be -- that --  
6 those would be reported as multiple AEs.

7 So, if -- what I think, if you're  
8 implying -- and I don't know if I'm -- maybe I'm not  
9 getting it correctly -- are these all from different  
10 patients, or could some of these be from the same  
11 patient?

12 But the answer is, I don't know from the  
13 printout here.

14 Q I'm not implying anything of the sort.

15 I'm asking if this is the kind of data that  
16 you would look at to determine that there were low  
17 mentions of Nucynta?

18 A These might be some of the data we would  
19 consider, yes.

20 Q Thank you.

21 Janssen evaluated speakers in its speaker  
22 program, right?

23 A I don't -- I would assume so, but I don't  
24 know.

25 Q You've received an evaluation as a speaker

1 for Janssen, right?

2 A I don't know. And I don't know how well I  
3 did.

4 Q Would you like to see it?

5 A Yeah, sure, why not?

6 Q Here is Exhibit 11.

7 (JAN-MS-00314736 through 745 was  
8 marked as Vorsanger 11 for  
9 identification, as of this  
10 date.)

11 A So, I'd like to point out that the third  
12 bullet says that I speak too slowly.

13 Q I was thinking of that when we first  
14 started this deposition.

15 A Okay.

16 Q You got a good/excellent grade.

17 A Thank you.

18 Q So, you have nothing to --

19 A Right, exactly.

20 Q -- be ashamed of with respect to this  
21 particular evaluation, at least.

22 So, the title of this document is  
23 "Janssen's Speaker Training Meeting," right?

24 A Yes.

25 Q Janssen held meetings at which it trained

1 its speakers?

2 A Yes.

3 Q And those speakers might be KOLs, right?

4 A They might be.

5 Q And they might just be practitioners in the  
6 speaker -- speakers' bureau?

7 A Yes.

8 Q In this particular meeting, there were 162  
9 attendees, right?

10 A That's what it looks like.

11 Q And it was held at the Hyatt Regency  
12 Scottsdale at Gainey Ranch in Scottsdale, Arizona,  
13 right?

14 A Yes.

15 Q In February 2003?

16 A Yes.

17 Q Do you remember this?

18 A I don't specifically remember the meeting,  
19 but I certainly see what's listed on the document.

20 The company subsequently got away from  
21 having meetings at these types of places.

22 Q Why?

23 A The company made a decision that having  
24 meetings at ranches and other types of things was  
25 something that they did not want to do. So, the

1 speaker training was held at more -- hotels, like  
2 Marriotts, and places like that.

3 Q It could be viewed as something that may  
4 influence the speakers who were being trained?

5 A I think it was also important that the  
6 environment that they be trained in enabled them to  
7 focus on it and not be able to be distracted by  
8 other types of things.

9 Q But you agreed, I think, because you  
10 shook -- nodded your head, that Janssen was  
11 concerned that by having speaker training programs  
12 held at locations like ranches or somewhere else  
13 might influence the attendees?

14 MR. LIFLAND: Objection to the form of the  
15 question.

16 A I don't know whether -- I don't know what  
17 the reason was, per se. But I think they felt that  
18 the other places would be more appropriate.

19 Q Why?

20 A I think that that was the environment that  
21 they could focus on that.

22 Q And Janssen did not want to be seen as  
23 conferring gifts on those in its speakers' program?

24 MR. LIFLAND: Object to the form of the  
25 question.



1           A     I don't know that -- how that worked. I  
2     don't know -- I don't recall whether they had gifts  
3     or didn't get gifts or any of those things.

4           Q     Well, paying for someone in the speakers'  
5     bureau to travel to and stay at a luxurious or  
6     exotic location could be viewed itself as a gift  
7     that may influence the speaker, right?

8           MR. LIFLAND: Object to the form of the  
9     question.

10          A     I don't know.

11          Q     You don't know?

12          A     Maybe. I don't know.

13          Q     Who is Steve Passik?

14          A     Steve Passik is a key opinion leader.

15          Q     Is he a physician?

16          A     I believe he's a Ph.D.

17          Q     What's he a key opinion leader about?

18          A     I'm sorry, I don't understand the question.

19          Q     What subject is he an expert on?

20          A     So, he is an expert in analgesia.

21          Q     That's the relief of pain?

22          A     Correct.

23          Q     But he's not a physician?

24          A     He's not a physician.

25          Q     Do you know what he has a Ph.D. in?

1 A I don't know.

2 Q What did Janssen do with the evaluations of  
3 the speakers?

4 A I don't know. I don't know what they did  
5 with it.

6 Q Okay.

7 A This was more -- this was speaker training  
8 that would have been run through marketing, and I  
9 don't know what marketing had done with the  
10 information.

11 Q Janssen wanted to have tapentadol  
12 down-scheduled from Schedule II to a lower schedule,  
13 right?

14 A That's not completely accurate. Janssen  
15 was investigating whether it would be appropriate to  
16 consider tapentadol to be down-scheduled.

17 Q Why would Janssen investigate that if it  
18 didn't want that to happen?

19 A Well, I don't know if it was a want as much  
20 as saying, was it -- did the data support  
21 down-scheduling? And if so, then that was something  
22 that they could investigate.

23 Q And that was viewed as something that would  
24 be good for tapentadol?

25 A It was something that would allow that the

1 product scheduling was consistent with the data that  
2 we had at the time, that would -- where the  
3 scheduled data would -- so, the compound was  
4 approved with a C2 status. The C2 status was such  
5 that it is an abuse potential.

6 And if the other -- if the additional data,  
7 once the product was on the market, would support a  
8 different schedule, then the company wanted to  
9 understand what that would look like and whether  
10 that was appropriate or not.

11 Q Yeah. And if Nucynta --

12 Which is tapentadol, right?

13 A Yes.

14 Q -- had been down-scheduled from C2 to C3,  
15 for instance --

16 A Yes.

17 Q Okay?

18 -- that would signal that Nucynta is less  
19 abusable than other opioids in C2?

20 A That would signal that the potential for  
21 abuse may be less.

22 Q All right.

23 A Not the actual abuse, the potential.

24 Q And that would be a good thing for  
25 Janssen's sales of Nucynta, right?

1           A       Well, I think the company's position was  
2       not related to sales at all, but to make sure that  
3       we now had a product -- because, remember, Vicodin  
4       in those days was also -- there was quite a lot of  
5       issues with Vicodin. And to have a product that  
6       has -- potentially having a lower abuse potential  
7       meant that an opioid analgesic might -- could  
8       potentially be used in the U.S. by prescribers for  
9       patients that had a potential for a lower abuse  
10      potential.

11          Q       Janssen also wanted to make a promotional  
12      claim that Nucynta had a reduced risk of misuse and  
13      abuse?

14               MR. LIFLAND: Object to the form of the  
15      question.

16          A       I don't recall that.

17          Q       Exhibit 12.

18                       (JAN-MS-02258276 was marked as  
19                       Vorsanger 12 for identification,  
20                       as of this date.)

21          Q       All right. This is an email that you wrote  
22      and sent in 2010, correct?

23          A       Yes.

24          Q       Do you see the sentence that starts, "Our  
25      objective"?

1 A Yes, I do.

2 Q Can you please read that sentence?

3 A Yes.

4 "Our objective is to gain insight from our  
5 advisors on the studies needed to generate  
6 scientifically compelling data on abuse, misuse, and  
7 diversion of tapentadol and Nucynta ER that may  
8 support down-scheduling tapentadol (currently C2),  
9 revising labeling for Nucynta ER, tamper-resistant  
10 formulation" -- okay. So, this would be a change to  
11 labeling based on scientific information -- "to  
12 allow promotional claims of reduced risk of misuse  
13 and abuse and publish a compelling body of evidence  
14 on the abuse, misuse, and diversion of tapentadol."

15 Q Okay. Thank you.

16 This sentence both references -- this  
17 sentence both references Janssen needing to generate  
18 scientifically compelling data --

19 A Yes.

20 Q Right?

21 -- for three reasons? Right?

22 Do you see those three reasons?

23 A Yes, that is correct.

24 Q Okay. The first is down-scheduling  
25 tapentadol, correct?

1 A If the data supported down-scheduling, yes.

2 Q The second one is "Revising the label for  
3 Nucynta ER to allow promotional claim of reduced  
4 risk of misuse and abuse," correct?

5 MR. LIFLAND: Object to the form of the  
6 question.

7 A If the -- if this information could be put  
8 in the product label, then it could be discussed  
9 with prescribers based on promotion.

10 Q Because Janssen has to promote based on  
11 what's in the label, right?

12 A Janssen needs to promote using  
13 company-approved materials.

14 Q Consistent with the label?

15 A Consistent with the label.

16 Q And the third reason was "publishing a  
17 compelling body of evidence on the abuse, misuse,  
18 and diversion of tapentadol"?

19 A Which would be part of the information from  
20 the clinical studies. That the studies would be  
21 done, and the data would be published.

22 Q That Janssen could generate scientifically  
23 compelling data to support those three things,  
24 right?

25 A Depending on what the studies showed, but

1 yes.

2 Q Okay. Thank you.

3 Nucynta carries a risk of addiction, right?

4 A Yes, it does.

5 Q Do you remember when you said earlier that  
6 Janssen should not omit information about the risks  
7 of addiction?

8 MR. LIFLAND: Object to the form of the  
9 question.

10 A I, I, I believe I testified that addiction  
11 is an important adverse event and that information  
12 needs to be information that prescribers need to be  
13 aware of, and patients.

14 Q It should be communicated, correct?

15 A Correct.

16 Q I'm going to hand you Exhibit 13.

17 (JAN-MS-00066073 through 095 was  
18 marked as Vorsanger 13 for  
19 identification, as of this  
20 date.)

21 Q Okay. Janssen employs a salesforce,  
22 correct?

23 A Yes.

24 Q Composed of sales representatives, right?

25 A Correct.

1 Q And this is a training document entitled  
2 "Nucynta ER Frequently Asked Questions for Sales  
3 Representatives," right?

4 MR. LIFLAND: Object to the form of the  
5 question.

6 A So, I don't know if this a draft or whether  
7 this is a final version. And I'm not -- I don't see  
8 specifically where it says that this was used with a  
9 salesforce. This just says "Nucynta ER Frequently  
10 Asked Questions."

11 Q Okay. Turn to page 8, please.

12 A Page 8?

13 Q Yes.

14 Do you see the box on page 8?

15 A Yes, I do.

16 Q What's the title of that box?

17 A "Note to sales representatives."

18 Q Does that help you answer my earlier  
19 question?

20 A If -- it may have been used -- yes.

21 MR. LIFLAND: Objection.

22 A It may have been used for internal  
23 training, but it may have been used for the  
24 salesforce.

25 But, again, as I commented, I don't know if



1 this was a final draft or not.

2 Q And it would be important to train sales  
3 representatives about the risks of addiction  
4 associated with Nucynta, right?

5 A Yes. And some of that would be information  
6 that would be in the product package insert, as  
7 well.

8 Q Are sales representatives required at  
9 Janssen to have a medical science degree?

10 A I don't know the answer to that question.  
11 I don't, I don't know what the requirements are  
12 today, and I don't know if they've changed or not.

13 Q Do you think that pharmaceutical package  
14 inserts are easy to understand for people without a  
15 science background?

16 A I think that, from my experience on using  
17 it, is that annotated package inserts were used to  
18 train sales reps, and those went through and took  
19 the language and put it in common language, where  
20 people could understand it.

21 So, this -- the statement that this was the  
22 document to train sales representatives is one that  
23 I don't agree with, because they would have all --  
24 this is a document --

25 Q A document.

1 A This a document. So --

2 Q I never said otherwise.

3 A Right. So, someone would have gone through  
4 and walked them through information from the package  
5 insert, as well.

6 Q These are -- according to this document,  
7 which there is nothing to suggest that I've seen  
8 this is a draft -- please correct me if you see  
9 something different.

10 A Well, it doesn't -- Counselor, it doesn't  
11 say "final." So, I -- my assumption is it could be  
12 a final or it may not be a final.

13 Q It doesn't say "draft," either, does it?

14 A All right. So, I don't know what its  
15 status is.

16 Q If you'll turn to page 2, there is a table  
17 of contents.

18 Do you see that?

19 A Yes.

20 Q There is no section entitled "Addiction."

21 A Not in this document.

22 Q Why not?

23 A I don't know. There may be -- as I've  
24 already testified, there may have been additional  
25 training from the package insert, which may have had

1 that.

2 This is some -- this is some information  
3 communicated to the salesforce.

4 Q On the first page, it states, "You may  
5 encounter the following questions when discussing  
6 Nucynta ER with customers."

7 Do you see that?

8 A Yes.

9 Q Customers are prescribers, correct?

10 A Yes.

11 Q Or maybe pharmacists, right?

12 A Those would also be customers, yes.

13 Q Okay. When Nucynta came out in -- what  
14 year?

15 A The immediate release was -- I think came  
16 to the U.S. marketplace in 2009.

17 Q Okay. By that time, according to this  
18 document, assuming this is a final document, Janssen  
19 did not believe that questions about addiction were  
20 being frequently asked.

21 MR. LIFLAND: Object to the form of the  
22 question.

23 A So, I, I haven't -- we haven't completely  
24 agreed this is a final document. We agreed it may  
25 or may not be.

1 Q Assume with me it is, according to this  
2 document.

3 A All right. And we also had agreed that --

4 MR. LIFLAND: Object to the form of the  
5 question.

6 A -- if I understood, there may have been --  
7 I had communicated that there were other documents  
8 that we used to train the salesforce.

9 Q Was there another Frequently Asked  
10 Questions Nucynta document?

11 A I don't know. I don't know.

12 Q This one doesn't have a section entitled  
13 "Addiction," does it?

14 A This particular document doesn't have a  
15 section on addiction.

16 Q Addiction is a big deal, isn't it?

17 A And it may --

18 MR. LIFLAND: Object to the form of the  
19 question.

20 A They may very well have been trained on  
21 addiction. That information is not in this  
22 document.

23 Q And Janssen should never omit information  
24 about addiction, should it?

25 MR. LIFLAND: Object to the form of the

1 question.

2 A Information should be transmitted, but may  
3 have been transmitted through education through the  
4 package insert or other modalities, as well.

5 Q Janssen should never omit information about  
6 addiction, should it?

7 A I think --

8 MR. LIFLAND: Object to the form of the  
9 question.

10 Q Can you answer my question? And if you  
11 want to say something afterwards, you can.

12 But Janssen should never omit information  
13 about the risks of addiction, should it?

14 A The answer is --

15 MR. LIFLAND: Object to the form of the  
16 question.

17 A -- Janssen needs to communicate all of the  
18 risks of opioid analgesics.

19 Q Including the risks of addiction?

20 A If --

21 MR. LIFLAND: Object to the form of the  
22 question.

23 A Depending on how, depending on how the  
24 conversation goes and what their -- how their sales  
25 reps are instructed to do it.

1 Q Are there any circumstances under which a  
2 sales representative should call on a physician and  
3 not discuss the risks of addiction --

4 A If a sales --

5 Q -- for Nucynta?

6 A If a prescriber was interested in  
7 addiction --

8 MR. LIFLAND: Object to the form of the  
9 question.

10 A -- they would then reach out specifically  
11 and have a medical information request sent, and  
12 that information could be sent.

13 So, that would be an opportunity or a  
14 situation in which a sales rep was not discussing  
15 it, because the prescriber may want more  
16 information, in which case a medical information  
17 request, if such a request existed, would be sent.

18 Q Well, what if the prescriber didn't reach  
19 out?

20 In your situation, we just have a sales  
21 call where addiction wasn't discussed, right?

22 A Or addiction may be something that's  
23 important enough that they may say, "We have a --  
24 specifically have a letter on addiction, or we have  
25 other company information on addiction. We would

1 like to send that to you."

2 So, I don't know the selling situation  
3 which took place. I'm unable to comment on your  
4 answer [sic].

5 Q Is there any situation you can think of  
6 where it would be appropriate for a Janssen sales  
7 representative to call on a physician and not say a  
8 word about the risk of addiction associated with  
9 Nucynta?

10 MR. LIFLAND: Object to the form of the  
11 question.

12 A If, if a physician was knowledgeable about  
13 opioids and had already received information on a  
14 previous visit, then a subsequent visit, they may  
15 not necessarily talk about addiction.

16 Q If the physician was knowledgeable about  
17 opioids already, didn't need to hear about addiction  
18 anymore, why was Janssen calling on them at all?

19 MR. LIFLAND: Object to the form of the  
20 question.

21 A Because as people use opioid analgesics,  
22 there are other questions that come up, and there  
23 may be other ways that -- new information that need  
24 to be shared.

25 Q When new information is shared, don't you

1 think doctors should be reminded about the addictive  
2 nature of opioids?

3 MR. LIFLAND: Object to the form of the  
4 question.

5 A I can't comment on the nature of the new  
6 information that it was going to be putting out. It  
7 depends on how much of the other information, et  
8 cetera.

9 Q Doctor, you would agree with me that, when  
10 it comes to addiction, Janssen can't be too careful  
11 with its promotional activities?

12 A I think --

13 MR. LIFLAND: Object to the form of the  
14 question.

15 A I think that the compounds that are being  
16 prescribed are known to have high -- be highly  
17 addictive. They're C2. That's defined in law. The  
18 individuals who are using these compounds require  
19 special licensing to be able to even prescribe those  
20 medications. Those people would be knowledgeable.

21 They may have been provided information in  
22 previous visits and subsequent visits, maybe new  
23 clinical trial data and other information, as well.

24 The nature of the call is such that that  
25 may be what needs to happen, and the physician --



1 and the prescriber -- it may not be a physician -- a  
2 prescriber themselves may request certain types of  
3 information that they want to hear about, as well.

4 So, the answer is, I have to qualify it,  
5 depending on the situation, and each one could be  
6 different.

7 Q It is impossible for Janssen to be too  
8 careful about the risks of addiction associated with  
9 its products?

10 MR. LIFLAND: Object to the form of the  
11 question.

12 A I'm not understanding what you mean in that  
13 context, sir.

14 Q I'm going to ask you again.

15 Janssen cannot be too careful when it comes  
16 to the risks of addiction associated with its opioid  
17 products?

18 A And that's --

19 MR. LIFLAND: Object to the form of the  
20 question.

21 A And that's why the information is  
22 communicated in the package insert and made  
23 available to prescribers to be able to have that.

24 Q And your testimony is: Providing the  
25 package insert is being careful enough about the

1 risk of addiction?

2 MR. LIFLAND: Object to the form of the  
3 question.

4 A There may have been also conversations that  
5 took place, and there is CME that the company has  
6 done. There are other routes and other ways that  
7 the company would communicate information on  
8 addiction.

9 Q Janssen should do as much as it possibly  
10 can to communicate the risks of addiction about its  
11 opioid products?

12 A Janssen did --

13 MR. LIFLAND: Object to the form of the  
14 question.

15 A Janssen needs to do what it considers to be  
16 appropriate, in terms of how the -- of the  
17 information that's been given to its prescribers.

18 Q Janssen shouldn't do the bare minimum?

19 MR. LIFLAND: Object to the form of the  
20 question.

21 A I'm sorry, I don't understand what you  
22 said.

23 Q Janssen should not do the bare minimum?

24 MR. LIFLAND: Object to the form of the  
25 question.

1           A       I never suggested that Janssen is doing the  
2 bare minimum.

3           Q       And not -- and Janssen shouldn't ever do  
4 the bare minimum --

5                   MR. LIFLAND: Object to the form of the  
6 question.

7           Q       -- when it comes to the risks of addiction?

8           A       I don't think there is a suggestion that  
9 Janssen ever did or is currently doing the minimum.

10          Q       You said you don't know what caused the  
11 opioid crisis, right?

12          A       I said that the opioid crisis was  
13 complicated and the root cause was not something  
14 that I know.

15          Q       And so, you can't testify here today  
16 whether or not Janssen was a cause of the opioid  
17 crisis, can you?

18          A       What I did testify earlier, Counselor, was,  
19 based on my analysis and the work that we did  
20 looking at mentions of abuse that took place from  
21 both products, for tapentadol and from Duragesic,  
22 from the time those products were introduced to the  
23 U.S. marketplace until 2005, when I did work with  
24 the compound, for Duragesic and for tapentadol, when  
25 the compound was sold to another company, I

1 observed, my team observed, using the methodologies  
2 that I've discussed, low mentions of abuse.

3 And those low mentions of abuse suggest to  
4 me that the Janssen compounds did not contribute to  
5 the opioid crisis.

6 Q So, you assumed something in my question I  
7 didn't say, which was that it was limited only to  
8 J&J compounds. I didn't say that. So, let me, let  
9 me restate my question. In fact, we'll break it  
10 down.

11 Johnson & Johnson and Janssen do more than  
12 just sell -- promote their own opioid products,  
13 right?

14 MR. LIFLAND: Object to the form of the  
15 question.

16 Q They engage in non-branded marketing?

17 A They engage in -- I'm sorry?

18 Q Non-branded marketing?

19 MR. LIFLAND: Object to the form of the  
20 question.

21 A They have engaged in non-branded marketing.

22 Q About opioids as a class of drug?

23 A They have engaged in non-branded marketing.

24 Q Okay. So, J&J's actions -- I'm not  
25 limiting my question to just opioid compounds that

1 J&J manufactured.

2 Do you understand that?

3 A Um --

4 Q And I'm going to ask the question again,  
5 but you understand I'm not limiting it to J&J  
6 opioids?

7 A You're talking about non-branded materials.  
8 The non-branded materials -- Counselor, so I'm  
9 clear, non-branded materials around opioids, is that  
10 what you're referring, or non-branded materials for  
11 any of their products?

12 Q Around opioids. This case is about  
13 opioids.

14 A Okay. So, you're referring to not the  
15 Janssen opioids, but non-branded material about  
16 opioids.

17 Q Let's back up.

18 Do you know what this case is about?

19 A Yes, sir, I do.

20 Q What is it?

21 A It's about opioid abuse and some of the  
22 problems.

23 But I'm just trying to understand your  
24 questions, Counselor.

25 Q Do you understand why your client is -- why

1 your former employer is being sued?

2 MR. LIFLAND: Object to the form of the  
3 question.

4 A I don't, I don't have the specifics of the  
5 case, no.

6 Q Have you looked at the petition in this  
7 case?

8 A I have not. No, I did not.

9 Q Are you able to sit here today and say that  
10 Janssen never did a single thing that contributed to  
11 the opioid crisis in this country?

12 MR. LIFLAND: Object to the form of the  
13 question.

14 A I believe that the -- as I've already  
15 testified, now on several occasions, that the  
16 medications did not contribute to the opioid crisis.

17 And I personally am not aware of any  
18 behaviors or activities that I could see trace  
19 specifically to the opioid crisis.

20 Q So, you don't know the particulars of what  
21 caused the opioid crisis, right?

22 A I don't know -- I -- my testimony is that  
23 the root cause of the opioid crisis is not something  
24 that I'm aware has been identified.

25 Q You just know that you don't think Janssen

1 had anything to do with it?

2 A Based on --

3 MR. LIFLAND: Object to the form of the  
4 question.

5 A Based on my experience of working at the  
6 company for 16 years and testifying as a witness of  
7 fact today, I haven't seen behaviors and I haven't  
8 seen data scientifically generated to suggest that  
9 that would have -- that would have contributed to  
10 the problem we have of substance abuse in the United  
11 States today.

12 Q You think we need data to determine that  
13 this opioid crisis was caused by the over-promotion  
14 by pharmaceutical companies like Janssen?

15 A I think --

16 MR. LIFLAND: Object to the form of the  
17 question.

18 A I think in order to identify what the cause  
19 of something is, I think we need to understand what  
20 are the activities and what are the data around it,  
21 rather than making an assumption.

22 Q Well, you don't -- is it your opinion that  
23 any decision made that's not based on hard data is  
24 an assumption?

25 A Not necessarily an assumption, but it's not

1 a decision that -- it would be a decision that I  
2 would have trouble following, if I didn't see the  
3 data to support it.

4 Q Because you're a man of science?

5 A Sorry?

6 Q Because you're a man of science?

7 MR. LIFLAND: Object to the form of the  
8 question.

9 A That's sort of our training, yes.

10 Q Sales representatives don't need a science  
11 degree, do they?

12 MR. LIFLAND: Object to the form of the  
13 question.

14 A Well, I think I testified that, for  
15 Janssen, I don't know whether they do or they don't.

16 Q You don't know.

17 Did you ever attend any Pain Care Forum  
18 meetings?

19 A I don't remember.

20 Q Do you know what the Pain Care Forum is?

21 A Not exactly. The name sounds familiar to  
22 me, Counselor. So, that's why I would say not  
23 exactly, because I'm not sure if I did or didn't.

24 Q Who is Burt Rosen?

25 A I don't know who Burt Rosen is.



1 Q Never heard of him?

2 A I don't know who he is.

3 Q All right. Do you remember the percentages  
4 of the rate of addiction you gave me earlier?

5 A (No verbal response.)

6 Q You said 1 and 4 -- or excuse me, you said  
7 1 to 4 percent.

8 A For iatrogenic addiction in patients who  
9 don't have an existing background -- I believe it  
10 was who are not complicated. And by that, I mean  
11 may not be substance abusers and may not have mental  
12 health disorders, yes.

13 Q Have you seen the request for production  
14 that Johnson & Johnson put out recently about  
15 studying the medical education needed around opioid  
16 prescribing?

17 A I have.

18 Q Okay. So, now you're retired, right?

19 A Yes.

20 Q Do you tell people that you -- when they  
21 ask, that you worked in and around the area of  
22 opioids?

23 A I do.

24 Q And when they ask, "Man, how did we get  
25 into this problem?" what do you tell them?

1           A     I told them what I told you today, that  
2     I --

3           Q     That you don't know?

4           A     That I -- it's a complex issue. The root  
5     cause has not been identified. And I know that  
6     that's still being worked on and discussed.

7           Q     Are you ashamed to tell people that you  
8     worked on opioids for so long?

9           A     No, not at all. I'm actually very proud of  
10    the fact, as an anesthesiologist, that I got to work  
11    on opioids.

12          Q     Really?

13          A     Yes.

14          Q     So, are you proud of the fact that  
15    companies like yours were able to sell so many  
16    opioids that we have an addiction, overdose, and  
17    abuse problem in this country?

18               MR. LIFLAND: Object to the form of the  
19    question.

20          A     Well, I've already testified that the  
21    cause, the root cause of the opioid crisis has not  
22    been identified, and I am very proud of the fact  
23    that I work at a company that's ethical and put out  
24    excellent products that helped many, many patients.

25               And as a matter of fact, one of the reasons

1     why I went into industry from private practice was  
2     to be able to do that, to advise companies in the  
3     safe and effective use of their medications.

4             So, I'm quite proud of the work that I've  
5     done.

6             Q     Were you aware that approximately  
7     80 percent of new heroin users started with  
8     prescription opioids?

9             MR. LIFLAND:   Object to the form of the  
10     question.

11            A     I would like to see the data to support  
12     that.

13            Q     I'm just asking if you're aware of it.

14            A     I'm aware that heroin users may have  
15     reported using prescription opioids, but I'm also  
16     aware of the fact that many of those individuals  
17     were substance abusers prior to using any of the  
18     type of opioids that they describe.

19            Q     Yeah, but they -- substance abusers existed  
20     whenever any of the prescription opioids launched,  
21     right?

22            MR. LIFLAND:   Object to the form of the  
23     question.

24            A     Substance abusers did exist before the  
25     opioids launched.

1 Q That's the market into which Janssen  
2 marketed its opioids, one that contained substance  
3 abusers.

4 A But Janssen made sure that we --

5 MR. LIFLAND: Object to the form of the  
6 question.

7 Just wait for me to --

8 THE WITNESS: Sure.

9 MR. LIFLAND: -- object before you start  
10 your answers.

11 THE WITNESS: Okay.

12 MR. LIFLAND: Thank you.

13 A Janssen respond -- marketed their products  
14 for patients with pain and marketed those to ensure  
15 that the drugs were used safe and effectively.

16 Yes, the abused market -- the substance  
17 abusers were around before these medications were  
18 available.

19 Q Do you believe that people who are addicted  
20 to opioids are bad people?

21 A No, I do not.

22 Q Do you think that they're just doing bad  
23 things to get a high?

24 MR. LIFLAND: Object to the form of the  
25 question.

1           A     I don't know what all their behaviors are.  
2     I think some people became addicted for a number of  
3     different reasons, and I don't always know -- and I  
4     don't know what many of those are.

5           Q     Do you pass any judgment on people who are  
6     addicted to opioids?

7           A     No, not at all. Absolutely not.

8           Q     Are you doing anything, now that you're  
9     retired, to assist with the opioid crisis?

10          A     Not specifically.

11          Q     Do you have any intention to?

12          A     Not at the, not at the moment. I would  
13     have to see what opportunities potentially come  
14     along. But not at the moment.

15                 MR. DUCK: All right. Let's take a break.

16                 THE VIDEOGRAPHER: Off, 12:58.

17                         (Recess taken.)

18                 THE VIDEOGRAPHER: We're back on, 1:59.

19          Q     Okay. I'm handing you what's been marked  
20     as Exhibit 14.

21                         (JAN-MS-02132383 through 387 was  
22                         marked as Vorsanger 14 for  
23                         identification, as of this  
24                         date.)

25          Q     All right. What is this document that is

1 Exhibit 14?

2 A What is it?

3 Q Yes.

4 A It looks like a discussion about a meeting  
5 that occurred with individuals from FDA, DEA, and  
6 individuals in various surveillance methodologies  
7 who attended a meeting. I don't know the date. I  
8 don't see the date on here. It says, "Date: Auto  
9 date," so, I don't know what it would be.

10 And there were members of representation  
11 from the various pharmaceutical industry, different  
12 companies.

13 And it looks like -- was it -- there's a --  
14 I don't know if this is a summary document that  
15 somebody prepared. May have been from the people  
16 who attended; John Thipphawong, Paul Kershaw, Kim  
17 Gaumer, and David Hewitt. It talked about the  
18 various people presented -- Bob Rappaport, who is  
19 formerly head of the division of anesthetics and  
20 critical care -- I'm not sure what they're called  
21 today -- Deborah Leiderman, who was in controlled  
22 substance; Judy Ball from DAWN, and several other  
23 people, as well, and it goes on and on -- David  
24 Joranson, etc.

25 And then people from RADARS -- Edgar Adams

1 we spoke about, I think; Ted Cicero; someone above  
2 him from Inflexxion; and some other -- James  
3 Inciardi was also from RADARS; and other people, as  
4 well.

5 Q Okay. You see the Alza logo in the top  
6 left?

7 A Yes, I do.

8 Q What is Alza?

9 A So, Alza is a company that formerly worked  
10 with J&J. I believe the Duragesic patch was created  
11 at Alza, made at Alza, and eventually Alza was  
12 bought by J&J.

13 Q Okay. So -- and that's what we've heard in  
14 prior testimony. I've just got a couple of  
15 questions.

16 Is Alza a -- was it a pharmaceutical  
17 manufacturer that J&J acquired?

18 A I believe so.

19 Q Okay. And they developed and manufactured  
20 Duragesic before J&J acquired Alza?

21 A Yes. That's my understanding.

22 Q And this memorandum is addressed to several  
23 people, including you.

24 A Yes, that's right.

25 Q And it's from John --

1 A Thipphawong.

2 Q Thipphawong?

3 A Yes.

4 Q Who is that?

5 A John Thipphawong was a medical director at  
6 Janssen.

7 Q Okay.

8 A John may have been at Alza at that point,  
9 and he went over to work at J&J. I'm not sure what  
10 his status was at the time, because I'm not sure  
11 what the date of the document was.

12 Paul Kershaw was at J&J. Kim Gaumer, I  
13 don't remember if she was at Alza or J&J. And David  
14 Hewitt was another medical director at Janssen.

15 Q Are all the people in the "To" line also  
16 J&J employees?

17 A Or they may have been at Alza.

18 Q Okay.

19 A Right.

20 Q Does any of the information you see on this  
21 first page give you any indication as to the  
22 approximate date of this document?

23 A No. I was trying to recollect when this  
24 would have occurred, as it would have passed along  
25 to me for informational purposes, but I don't. I



1 don't know.

2 Q Does Alza still exist?

3 A No. Alza was acquired by J&J, and I think  
4 whatever activities were going on were taken in by  
5 J&J. So, I don't know -- I don't think they're  
6 freestanding anymore, I'm not sure, but I don't  
7 think so.

8 Q What year did J&J acquire Alza?

9 A I don't know. We'd have to look that up.

10 Q In the '90s?

11 A I don't recall. I mean, I don't recall.

12 Q Okay. By the time you joined Janssen,  
13 Duragesic was already part of the Janssen portfolio?

14 A Well, Duragesic was part of the Janssen --  
15 it was marketed by Janssen, but it may have been  
16 manufactured by Alza.

17 Q Okay. Did Alza ever market Duragesic?

18 A I don't believe so. I think Janssen, or  
19 J&J, would have marketed it. Alza was more of a  
20 discovery company and created those types of --

21 Q Are you familiar with any other drugs  
22 created by Alza?

23 A Not that come to mind very quickly.

24 Q What about kind of slowly?

25 A Even kind of slowly.

1 Q You can't think of any other ones, in other  
2 words?

3 A Not offhand.

4 Q Okay. Do you know if Alza created any  
5 other opioid products?

6 A I don't recall, Counselor.

7 Q And I'm not asking for a name.

8 Just generally, do you know that?

9 A I don't remember what -- their portfolio of  
10 medications and what other things that they worked  
11 on. They may have worked on one of the successor  
12 compounds for -- potential successor compounds, but  
13 I'm not certain about that.

14 Q Okay. Thanks.

15 If you'll turn to page -- it's page 2.

16 A Uh-huh.

17 Q You'll see that Bob Rappaport is listed  
18 there?

19 A Yes.

20 Q And he's from the FDA?

21 A That's correct.

22 Q Did you know Bob Rappaport?

23 A I knew of him, but I did not know him well  
24 at all.

25 Q Do you recall this meeting at all?

1 A Excuse me. I don't.

2 Q Do you recall the name of the group that  
3 attended this meeting?

4 A You mean was there a group that was formed  
5 and that those individuals went to it? I don't.

6 It looks like there are people from a  
7 variety of different backgrounds; so, I don't know  
8 if they were part of a specific group or not.

9 Q There's a symposium mentioned on the page,  
10 on the first page.

11 Is that what this is reflecting?

12 A It looks like it. It looks like they  
13 called it -- the opioid risk management meeting a  
14 symposium. That's what it looks like.

15 But I'm not sure if there was another  
16 meeting that was convened, as well. I don't know.

17 Q Okay. Thank you.

18 Do you know if Bob Rappaport still works at  
19 the FDA?

20 A No. Bob Rappaport, I believe, retired from  
21 the FDA. And I think the person who took over his  
22 position is Sharon Hertz, but I don't know whether  
23 Sharon is still there or not. But she was his  
24 immediate successor, as far as I recall.

25 Q When he left the FDA, he retired and didn't

1 work anywhere else?

2 A I believe he did consulting work, but I  
3 would have to confirm that.

4 Q Did he do consulting work for Janssen?

5 A Not that I recall. I mean, he might have  
6 worked for another division but not with me, not in  
7 the work that I did.

8 Q Did you interact directly with employees of  
9 the FDA?

10 A Not specifically while they were at the  
11 FDA. We may have attended meetings where there was  
12 representation from FDA and other governmental  
13 agencies, at a meeting like ACTION or some of the  
14 other meetings. That would have been where we  
15 potentially might have had interactions with them.

16 Q Were you involved in the launch of Nucynta?

17 A I was involved in the launch of Nucynta,  
18 yes.

19 Q Did the medical affairs group for opioid  
20 analgesia assist with the launch?

21 A We would have provided scientific  
22 information as requested. And if there was any  
23 training that would have needed to be done, we would  
24 have done that, as well. And we, of course, had  
25 individuals working on the promotional review

1 committee to review materials that would have been  
2 used for the launch.

3 Q Did you and your group assist with  
4 obtaining FDA approval for Nucynta?

5 A Not specifically. The FDA approval for  
6 Nucynta would have been done by our research and  
7 development group, predominantly.

8 If they wanted additional information or  
9 scientific input, then we would have done that.

10 But the approval of the product would have  
11 been the predominant role of the research and  
12 development group.

13 Q At what point does the research and  
14 development group hand over the scientific research  
15 projects to medical affairs?

16 A So, once a product -- in the United States.  
17 So, once the product is approved, then  
18 responsibilities for that -- for marketed products  
19 would be going to U.S. medical affairs.

20 If there were post-approval studies that  
21 were needed by the FDA -- so, if FDA said, "This is  
22 great, it's approved, but there are more studies we  
23 would like you to do" -- those studies would be done  
24 by the research and development group.

25 Q Understood. Thank you.

1           You see Bob Rappaport says in -- there are  
2     some bullet points that are summarizing what he  
3     said.

4           Do you see that?

5           A     I do.

6           Q     Number 6 says, "Major issues with  
7     evaluating effectiveness of RMP."

8           What, what does "RMP" mean?

9           A     A "risk management program."

10          Q     Okay. And are any -- well, are any of --  
11     new question.

12          Was Duragesic required to have an RMP?

13          A     Yes.

14          Q     Was Duragesic later required to have a  
15     REMS?

16          A     Yes, that's right.

17          Q     Number 7, Bob Rappaport indicates that it's  
18     unclear what rate of addiction you would expect in  
19     legitimate pain patients.

20          Do you see that?

21          A     I do.

22          Q     Do you agree with that?

23          A     I don't know the timing on when this was  
24     done, of when the meeting took place. So, I don't  
25     know whether -- what -- the published literature

1 that came out after the meeting, where more  
2 information -- more studies might have been done, et  
3 cetera. So, I don't --

4 Q Was Duragesic more addictive in 1990, when  
5 it was approved, than it is today?

6 MR. LIFLAND: Object to the form of the  
7 question.

8 A So, I'm not sure what the current rates of  
9 addiction would be and what it would be. The  
10 current formulation is not the reservoir patch that  
11 was the case in 1990.

12 From studies that were done looking at  
13 reservoir patch, the original Duragesic patch, and  
14 the matrix technology which was used for transdermal  
15 fentanyl, the Janssen follow-on product, rates of  
16 abuse were low for both formulations.

17 Q Was fentanyl less addictive in 1990 than it  
18 is today?

19 A So, fentanyl --

20 MR. LIFLAND: Object to the form of the  
21 question.

22 Go ahead.

23 A So, fentanyl, as a compound, is still a C2.  
24 So, the potential of abuse for the compound stays  
25 the same.

1 But as I testified earlier today, there are  
2 other considerations of abuse. And we talked about  
3 the formulation, the delivery systems, et cetera.

4 Q So, fentanyl, as a Schedule II controlled  
5 substance, was just as addictive in 1990 as it is  
6 today?

7 A Yes.

8 Q What are the chances that a pain patient  
9 will get addicted? Do you understand that to be  
10 different than the current rate of addiction?

11 MR. LIFLAND: Object to the form of the  
12 question.

13 Q Do you understand my question?

14 A So, the chance -- the chance -- so, for an  
15 individual patient, that needs to be individualized.

16 So, as we talked about this morning, it  
17 depends, on part, on their past medical history.  
18 So, if they have a history of substance abuse, if  
19 they have a history of mental illness, then the  
20 rates, projected rates of addiction from an opioid  
21 medication prescribed to them would be higher than  
22 someone who does not have a history of mental  
23 disorder or substance abuse.

24 Q How much higher?

25 A I'd have to look at the publications that



1 looked at that and stratify that based on it. I  
2 don't have the numbers at my fingertips.

3 But we know -- and, in fact, our product is  
4 labeled for the fact that those are risk factors  
5 that do increase the risk of iatrogenic addiction.

6 Q So, if I walked into your office and you're  
7 a practicing physician, and I told you the truth  
8 about my entire medical history, you could take that  
9 information, run some tests, and tell me, "Okay,  
10 Trey, you have X percent chance to get addicted to  
11 opioids"?

12 A I don't know that we would be able to give  
13 you a percentage. We would say that you're at  
14 increased risk for addiction because of the issues  
15 that we had just spoken about.

16 And then I would make sure that I would  
17 do -- my interaction with you and how I would follow  
18 you medically might be different.

19 For example, I might see you more  
20 frequently, I might check in and see how you're  
21 using medications. Somebody like that, we may do  
22 more frequent urine toxicology screens, to see not  
23 only if you're using the medicines that I prescribed  
24 to you, but if you're using illegal medications. I  
25 might set you up with someone who is a counselor,

1 who can work with you to help you with some of the  
2 psychological issues you have that may  
3 predistribute -- that -- because you're predisposed  
4 to it.

5 So, I wouldn't be able to give you a  
6 number, but I would work with you to show the types  
7 of things we could do to help you to make sure that  
8 the medication is used safely and effectively.

9 Now, having said that, I would also see  
10 whether an opioid analgesic was the best medication  
11 for you. It may be that other medications are  
12 better and opioids would not be the best medicine.

13 But we would follow you carefully. And if  
14 we saw signs of addiction that were going on, then  
15 we might either change the medication, use other  
16 medications.

17 So, it's an ongoing process between the  
18 medical doctor and the patient as we went along to  
19 do that.

20 Q Okay. So, everything you just said would  
21 be required.

22 That is what Janssen expects physicians to  
23 do with every patient that walks in with pain?

24 A So, my comment to you was, what would be  
25 good clinical practice to care for a patient who is

1 at an increased risk. It's not -- I'm not speaking  
2 on what the company's expectations are.

3 You asked me as a clinician, someone coming  
4 into my office, what would I do or what would be  
5 looked at. And those would be the types of steps  
6 that I would do.

7 Q And that's what you think every physician  
8 should do with every patient that comes in with  
9 pain?

10 A I think that that would be the type of care  
11 that I would give patients coming into my -- if I  
12 was in practice today doing something like that.

13 Q A lot of work involved with prescribing an  
14 opioid?

15 A There is, and especially for individuals  
16 with increased risk.

17 Q You would agree that opioids are not a  
18 risk-free panacea for chronic pain?

19 A For?

20 Q Chronic pain.

21 A Every medication has its challenges that  
22 you give the patients. There are adverse events  
23 associated with them, and you need to make sure that  
24 whatever therapy you embark on with the patient to  
25 treat their chronic pain, that you explain the risks

1 to patients, that they understand the risks, and  
2 that you monitor patients carefully and continually  
3 on an ongoing basis to be able to do that.

4 Q So, my question is: You would agree that  
5 opioids are not a risk-free panacea for chronic  
6 pain?

7 A Opioids are not risk-free; they have known,  
8 defined risks, yes.

9 Q They are not a cure-all for chronic pain?

10 A They are not a cure-all for chronic pain.  
11 They may be used in conjunction with other medical  
12 therapeutic treatment for chronic pain, as well.

13 Q Opioids do not heal the underlying disease  
14 state causing the pain?

15 A Depending on the nature of the disease,  
16 yes, that may be true.

17 Q Is there any disease that you're aware of  
18 that opioids heal?

19 A Not for the chronic pain, no.

20 Q Is there any disease at all that you're  
21 aware of that opioids heal?

22 A Not specifically the disease; the symptoms  
23 of a disease: Pain.

24 Q Who is Cynthia McCormick?

25 A Cynthia McCormick was head of anesthetics

1 and life support -- again, that's the division. I  
2 don't -- I'm paraphrasing the title of the division  
3 at FDA. She was the predecessor of Bob Rappaport;  
4 she was his boss.

5 Q Okay. If you'll turn to page 4, do you see  
6 the bold language attributed to Cynthia McCormick?

7 A Yes, I do.

8 Q Can you please read that?

9 A "Cynthia McCormack [sic] raised concern  
10 that risk -- RMP and other interventions do not seem  
11 to have reduced OxyContin abuse based on available  
12 surveillance data"-- and in parentheses --  
13 "(potential implications for new opioids licensed  
14 with restricted distribution, e.g., Palladone, due  
15 to the need to assess success of RMP)."

16 Q Thank you.

17 What is Inflexxion?

18 A Inflexxion is a company based in  
19 Massachusetts that does surveillance for abuse of  
20 opioids, amongst other activities that they do.

21 Q Does Inflexxion support RMPs?

22 A The data that may be used from Inflexxion  
23 could be used to inform the RMPs.

24 Q If you'll turn the page to page 5, you see  
25 James Inciardi.

1 We've seen his name before today, right?

2 A That's correct, yes.

3 Q In association with RADARS data, right?

4 A Yes.

5 Q You'll see that there is a bullet point  
6 under James Inciardi's name that says "Diversion is  
7 a 25 billion-dollar industry," right?

8 A I see the bullet point.

9 Q Have you seen that figure before?

10 A I have not. I might have seen it when I  
11 looked at this document, whenever it came out,  
12 because my name was on it, but it's not a number  
13 that I'm that familiar with.

14 Q At the very bottom, you'll see that there  
15 are additional comments?

16 A Yes.

17 Q It states, in the third bullet point,  
18 "Prescription drug abuse rising disproportionately  
19 in the past decade."

20 Correct?

21 A Yes.

22 Q And then there are three subpoints.  
23 "Particularly in young" is the first one?

24 A Uh-huh.

25 Q And then the second one says, "Opioids

1 becoming drug of choice for abuse."

2 Do you see that?

3 A Yes.

4 Q Do you disagree with anything that we just  
5 read there?

6 A I would need to see the data sources that  
7 supported that. So, I don't know where those  
8 conclusions came from.

9 Q Have you seen any data that, while you were  
10 working at J&J or Janssen, showed that prescription  
11 drug abuse was rising disproportionately?

12 A I don't know if it's rising  
13 disproportionately. I think I have seen data  
14 talking about use in young people and that there may  
15 be more in, let's say, the younger category, but I  
16 don't know that I saw data showing rising  
17 disproportionately.

18 Q Do you remember seeing data that opioids  
19 were becoming the drug of choice for abuse?

20 A I don't remember scientific data, although  
21 there certainly could have been. I think there was  
22 mention in some of the lay press about that, but  
23 that would be the best of my recollection.

24 Q Are you distinguishing between the word  
25 "data" I used and "scientific data," which is what

1 you used?

2 A Yes.

3 Q Were you aware of any data, while you were  
4 working at Janssen, that showed opioids were  
5 becoming the drug of choice for abuse?

6 A As compared --

7 MR. LIFLAND: Object to the form of the  
8 question.

9 A I didn't have comparative data for drugs  
10 such as heroin, I think, or illegal. So, I don't, I  
11 don't, I don't recall.

12 Q If you'll turn to the first page, there's  
13 reference to David Joranson, University of  
14 Wisconsin.

15 Is that the same Joranson who did the DAWN  
16 study that we talked about earlier?

17 A I believe so.

18 Q Where did Janssen get the APIs to  
19 manufacture its opioids?

20 A I believe that it came -- that the  
21 medication, the API came from Noramco.

22 Q Noramco is -- was a subsidiary of Johnson &  
23 Johnson, correct?

24 A It was a J&J company, yes.

25 Q Do you have an understanding of whether or



1 not Noramco supplied other manufacturers of opioids  
2 with APIs?

3 A That's what I heard. I hadn't seen it. I  
4 didn't work with Noramco. They were not part of my  
5 responsibility. So, what I know is that it was a  
6 J&J company, as I've just testified, and they  
7 provide API to other pharma companies, but I don't  
8 know which companies those were.

9 And that's pretty much what I know about  
10 it.

11 Q You didn't know that Noramco supplied  
12 Purdue with oxycodone?

13 A I didn't know that they --

14 MS. NEWSOME: Objection to form.

15 A -- specifically supplied Purdue. As I just  
16 testified, I know they supplied other pharmaceutical  
17 companies, but I wasn't sure which ones.

18 Q You're aware that Johnson & Johnson created  
19 a poppy that allowed for the prolific --  
20 proliferation of oxycodone?

21 MR. LIFLAND: Object to the form of the  
22 question.

23 A I'm not aware of that.

24 Q You're not aware of the high-thebaine  
25 poppy?

1 A I am not.

2 MR. LIFLAND: Object to the form of the  
3 question.

4 Q Sorry, can you say --

5 A No, sir, I'm not.

6 Q Okay. Are you aware of a company called  
7 Tasmanian Alkaloids?

8 A I've heard of the name of the company.

9 Q What is it? What do you know about it?

10 A That they obtain alkaloids, I believe, from  
11 Tasmania. That's pretty much the extent of what I  
12 know about what they do.

13 Q Well, you knew it was a Johnson & Johnson  
14 company?

15 A I did not know that that was a J&J company,  
16 no.

17 Q You didn't?

18 A I did not.

19 Q Have you ever heard of the Norman poppy?

20 A No, I have not.

21 Q Have you ever received any training, while  
22 you were at Janssen, about how poppies are grown and  
23 how the opium is extracted from the poppies?

24 A Not to the best of my recollection.

25 Q You haven't received any training on the

1 development of certain poppies to increase the  
2 supply of opioid APIs?

3 MR. LIFLAND: Object to the form of the  
4 question.

5 A Not that I recall, no.

6 Q Sir, do you agree that there is an  
7 oversupply of opioids in the United States today?

8 MR. LIFLAND: Object to the form of the  
9 question.

10 A No, I don't.

11 Q You think there's just the right amount of  
12 opioids in the market today?

13 A My understand --

14 MR. LIFLAND: Object to the form of the  
15 question.

16 A My understanding is that the supply of  
17 opioids is regulated by the DEA. The DEA monitor  
18 it, are in a best position to understand what the  
19 supply requirements are and what the demand  
20 requirements are.

21 So, I don't have an opinion, other than the  
22 fact that it's heavily regulated through DEA.

23 Q DEA has no supply requirements.

24 A No, they look and see -- they will look and  
25 see what the supply needs of the country are, and

1 then will understand when more drug may be needed.

2 Q And they get input from pharmaceutical  
3 companies to understand that need, right, sir?

4 A That's my understanding.

5 MR. LIFLAND: Object to the form of the  
6 question.

7 A That's my understanding.

8 Q But the DEA does not require any company to  
9 manufacture an opioid product?

10 MR. LIFLAND: Object to the form of the  
11 question.

12 A I don't know what the processes are for the  
13 DEA.

14 Q DEA doesn't require Janssen to supply a  
15 certain volume of opioids each year?

16 MR. LIFLAND: Object to the form of the  
17 question.

18 A As I mentioned, I don't know the processes  
19 around how DEA works. I just testified on what I  
20 have -- what I know.

21 Q You have no idea?

22 A I do not.

23 Q But it's your testimony that there's not an  
24 oversupply?

25 A I believe that the supply would be correct,

1 because I think DEA has been do -- is in a position  
2 to understand what the supply needs are and what the  
3 requirements are.

4 Q You mean the DEA, that's lobbied by  
5 pharmaceutical companies who manufacture opioids,  
6 should know exactly what the needs are?

7 A I think --

8 MR. LIFLAND: Object to the form of the  
9 question.

10 A I think the DEA is heavily regulated. I  
11 think these processes are heavily regulated. It's  
12 not my area of expertise; so, I don't know the  
13 specifics around it.

14 Q Is it even possible for there to be an  
15 opioid abuse, addiction, and overdose crisis if  
16 there's not an oversupply of opioids?

17 MR. LIFLAND: Object to the form of the  
18 question.

19 A Well, the opioid crisis is not only -- may  
20 not only be related to what opioids are produced by  
21 pharmaceutical companies.

22 Q It's primarily related to that, sir. You  
23 would agree with that.

24 MR. LIFLAND: Object to the form of the  
25 question.

1 Q There is a prescription opioid crisis in  
2 this country.

3 MR. LIFLAND: Object to the form of the  
4 question.

5 A My understanding is that the opioid crisis,  
6 today, is fueled largely from illegal -- drugs like  
7 illegal fentanyl.

8 Q Who told you that?

9 A That's what -- my understanding from  
10 reading in the lay press.

11 Q Okay. So, I think we've had a  
12 miscommunication today.

13 Are you aware that there is a prescription  
14 opioid crisis in this country?

15 MR. LIFLAND: Object to the form of the  
16 question.

17 A I'm aware of the fact that there is -- that  
18 there is a crisis of substance abuse. Some of that  
19 involves prescription medications.

20 But to my reason, my understanding, a lot  
21 of the opioid crisis today is being fueled by  
22 illegal medications.

23 Q And your testimony is that if you take the  
24 illegal opioids out of the equation so that there  
25 are only prescription opioids in this country, we

1 wouldn't have a crisis?

2 A No, I didn't say that, nor did I imply  
3 that.

4 Q Okay. Because that wouldn't be right,  
5 would it?

6 A Well, I --

7 MR. LIFLAND: Object to the form of the  
8 question.

9 A Yeah. You had asked me a question, that I  
10 think I understand, was: The crisis is fueled by  
11 prescription drugs.

12 And I think my -- my understanding is that  
13 there are other forms of opioids that are also  
14 fueling the crisis, as I've just testified.

15 Q And you listed heroin and fentanyl?

16 A Yes.

17 Q Are you aware of the outbreak of heroin  
18 epidemics in this country?

19 A I know that heroin is widely abused in the  
20 country.

21 Q There was no heroin epidemic in the 1990s,  
22 when OxyContin hit the market, was there?

23 A I --

24 MR. LIFLAND: Object to the form of the  
25 question.

1 A I don't know.

2 Q Do you know what an epidemic is?

3 A I do.

4 Q There was no heroin crisis when OxyContin  
5 hit the market in the 1990s, was there?

6 A I don't know that. I don't know.

7 Q There was no heroin crisis when Duragesic  
8 launched?

9 MR. LIFLAND: Object to the form of the  
10 question.

11 A I would need to go back and look at the  
12 available data to be able to comment on that.

13 Q You don't know, one way or another?

14 A I don't know at this time.

15 Q You don't know how much heroin is being  
16 used today?

17 A No, I don't.

18 Q You don't know how much fentanyl is being  
19 used today?

20 A Not offhand, not directly.

21 Q You don't know what percentage of the  
22 opioid crisis is attributable to prescription  
23 opioids, do you?

24 MR. LIFLAND: Object to the form of the  
25 question.



1           A     No, I don't. I just testified on what I  
2     had read recently, that a lot of it is being fueled  
3     by illegal opioids.

4           Q     What did you read? What source?

5           A     Just that. Some scientific data. Maybe  
6     some of the lay press.

7           Q     You're aware that, when it comes to  
8     addictive substances, that oversupplying a market  
9     can create a voracious appetite for that addictive  
10    substance?

11           MR. LIFLAND: Object --

12           Q     You're aware of that as a concept?

13           MR. LIFLAND: Object to the form of the  
14    question.

15           A     Could you repeat the question?

16           Q     Yeah.

17                 If you oversupply addictive substances,  
18    that can create a voracious demand for that  
19    substance in the market, can it?

20           MR. LIFLAND: Object to the form of the  
21    question.

22           A     Do you have a reference for that, that I  
23    can read -- can see?

24           Q     Opioids oversupplied --

25           A     Yes.

1 Q -- create an increased demand for opioids.

2 MR. LIFLAND: Object to the form of the  
3 question.

4 A Yes. So, I would like to see a reference  
5 that supports that statement.

6 Q I'm asking you as a --

7 A No, I haven't seen it.

8 Q -- logical question, doesn't that make  
9 sense?

10 A I would need to see the support for the  
11 statement in order to -- you asked me do I agree,  
12 and my answer is: I would need to see the  
13 scientific support to be able to agree with it or  
14 disagree with it.

15 Q You can neither agree nor disagree?

16 A At this time, I can neither agree nor  
17 disagree, in the absence of the data.

18 Q Do you have any understanding of supply and  
19 demand in markets for opioids?

20 MR. LIFLAND: Object to the form of the  
21 question.

22 A I'm not sure I understand what that -- what  
23 you're asking me.

24 Q Do you understand how the economics of  
25 supply and demand work with respect to opioid

1 products?

2 MR. LIFLAND: Object to the form of the  
3 question.

4 A I don't know that they're different from  
5 supply and demand in any other markets. But there  
6 may be differences that I'm not aware of.

7 Q So, you don't know how the fact that  
8 opioids are addictive may affect principles of  
9 supply and demand?

10 MR. LIFLAND: Object to the form of the  
11 question.

12 A I don't know specifically what -- how  
13 addiction would impact on those.

14 Q Janssen has stopped marketing opioids,  
15 right?

16 A I don't know if they're continuing to  
17 market generic forms of fentanyl or not. I simply  
18 don't know. I'm not connected to that, and I don't  
19 know if they're continuing to market tramadol or  
20 not.

21 Q Janssen, at one point, has marketed generic  
22 fentanyl?

23 A Sorry? There was a generic form, I think,  
24 of fentanyl that was out at one point, but I don't  
25 know if it's still being marketed or not.

1 Q What was it called?

2 A I don't know.

3 Q Like a fentanyl patch?

4 A I think they were marketing under the  
5 branded name of Duragesic, but I think they had  
6 authorized generics, as well -- an authorized  
7 generic, as well.

8 Q But it was a Duragesic-style generic?

9 A Yes, it was.

10 Q Okay. Janssen divested of Nucynta while  
11 you were still there, correct?

12 A That's correct.

13 Q Why did Janssen divest of Nucynta?

14 A I don't know.

15 Q You have no idea?

16 A I don't know why.

17 Q What year was that?

18 A And the dates are approximate. I want to  
19 say about 2015 or thereabouts.

20 Q Okay. There was an opioid crisis in 2015?

21 MR. LIFLAND: Object to the form of the  
22 question.

23 A There were reports of substance abuse. And  
24 there was -- certainly, in the lay press, the opioid  
25 crisis was reported.

1 Q All right. And did Janssen divest of  
2 Nucynta to help address the opioid crisis?

3 MR. LIFLAND: Object to the form of the  
4 question.

5 A So, I just testified I don't know the  
6 reason for why they sold the product.

7 Q So, no, you don't know?

8 A I just said I don't know why they sold the  
9 product. I don't know what the reason was for why  
10 they sold the product.

11 Q Who would know that?

12 A I don't know.

13 Q Do you have any idea?

14 A No, I don't. Somebody from the  
15 commercial -- like somebody in the commercial group  
16 maybe, but I don't know.

17 Q So, if you were still working at Janssen  
18 and you wanted to find that out, who would you ask?

19 A I don't know at this point.

20 Q No --

21 A Even if I were working there -- I  
22 understand -- I don't know specifically who I would  
23 go to for that.

24 Somebody in senior management, but I don't  
25 know even who that would be.

1 Q At the time of the divestiture, who would  
2 that have been?

3 A The president of the company at that point  
4 would maybe have known.

5 Q Who was that then?

6 A I don't know. We'd have to look that up  
7 for you. I don't remember.

8 Q Okay, thank you.

9 Today, Janssen and Johnson & Johnson have  
10 no public ties to opioids?

11 MR. LIFLAND: Object to the form of the  
12 question.

13 A Yeah, I don't know. I don't follow that  
14 very much; so, I don't know. I'm not at the company  
15 anymore, and I don't -- so, I don't know.

16 Q All right. Janssen no longer markets  
17 Duragesic, the branded form Duragesic, right?

18 A I don't --

19 MR. LIFLAND: Object to the form of the  
20 question.

21 A Yeah, as I commented, I'm not keeping up on  
22 what currently is being done in the opioid space at  
23 the company. So, I'm not able to answer your  
24 question if they are or are not marketing Duragesic.  
25 I don't know.

1 Q Okay. Let's go to the day before you left  
2 Janssen, okay?

3 At that point in time, J&J was no longer  
4 marketing branded Duragesic, correct?

5 A I don't know. As I mentioned and  
6 testified, I was working in infectious disease  
7 group; I did not have ties to the analgesia group.  
8 So, I don't know specifically what activities were  
9 going on about Duragesic.

10 Q Did Janssen ever stop marketing Duragesic  
11 while you were there?

12 A I don't know at the very end, in 200 --

13 Q No. Any time you were there, did Janssen  
14 ever stop marketing Duragesic?

15 A No. When I was there, to the best of my  
16 recollection, the product was being sold.

17 Q Okay. Did Janssen ever stop promoting  
18 Duragesic?

19 A When the product went generic in 20 --  
20 sorry, in 2005, I believe that there was a tapering  
21 off of promotional activities, but I don't know when  
22 they stopped completely.

23 Q But you know that ultimately they stopped  
24 promoting Duragesic?

25 A That was my understanding.

1 Q Okay. Thank you, sir.

2 So, Janssen stopped promoting Duragesic,  
3 right?

4 A Yes.

5 Q Janssen divested of Nucynta, correct?

6 A Yes.

7 Q And you understand, sir, that Janssen sold  
8 Noramco?

9 A That's correct.

10 Q Thank you.

11 MR. DUCK: I'll pass the witness.

12 MR. LIFLAND: Okay.

13 MR. WEISBAND: Let's take a five-minute  
14 break.

15 MR. LIFLAND: Just five minutes to get  
16 ready.

17 THE VIDEOGRAPHER: We're off, 2:39.

18 (Recess taken.)

19 THE VIDEOGRAPHER: Back on, 2:43.

20 EXAMINATION BY

21 MR. LIFLAND:

22 Q Good afternoon, Dr. Vorsanger.

23 A Good afternoon.

24 Q You've already given a description of your  
25 general background earlier this morning. So, I'd



1 like to try to move this -- through this quickly  
2 with just a few questions.

3 A Sure.

4 Q You're a medical doctor?

5 A Yes.

6 Q And your medical education is what?

7 A My -- well, I went to medical school, and I  
8 was trained in both internal medicine and  
9 anesthesiology, and I'm board certified in both.

10 Q And that was approximately when?

11 A So, my -- I was at medical school, as I  
12 testified, from 1980 to 1984. From 1984 to 1987, I  
13 did my internal medicine training; I did an  
14 internship and residency. From 1987 to 1990, I did  
15 a residency in anesthesiology at the Massachusetts  
16 General Hospital.

17 Q Can you explain briefly what's involved in  
18 an anesthesiology residency?

19 A Yes. So, an anesthesia -- anesthesiology  
20 residence, physicians learn how to administer the  
21 various anesthetic agents in -- either to treat  
22 chronic pain or in the operating room. It's to keep  
23 patients comfortable, monitor vital signs, and give  
24 them medicines to treat pain and keep them pain-free  
25 during surgeries.

1 Q And after your residency, I think you said  
2 you were a practicing anesthesiologist?

3 A That's correct.

4 MR. DUCK: Objection to form.

5 A I was invited to come on staff as a staff  
6 anesthesiologist at Massachusetts General Hospital.  
7 I was there for several years, from about 1990 to  
8 1993. And then from 19 -- and the dates are  
9 approximate. From 1993 to 1995, I worked in  
10 anesthesia private practice.

11 Q And where did you go after that?

12 A After that, I transitioned to work at Astra  
13 USA, as I have testified.

14 Q And just briefly, what did you work on  
15 there?

16 A So, at Astra USA, I was a medical advisor,  
17 as I mentioned, and I worked on helping them develop  
18 their local anesthetic, Novocaine-like medication.

19 Q And how about after Astra?

20 A So, after Astra, I worked at a company  
21 called Parexel. It's P-A-R-E-X-E-L. It's a  
22 contract research organization.

23 Q And why did you go to Parexel?

24 A Parexel, as a company -- it's Parexel  
25 International -- is a place where I learned a lot

1 about clinical trial methodology, how to write  
2 protocols, how to conduct clinical trials, and  
3 provide -- and learn about safety monitoring for  
4 patients in clinical trials, to take data from those  
5 studies and learn, in part, how to analyze and use  
6 that information.

7 Q Did you do any work with Janssen at  
8 Parexel?

9 A I did.

10 Q Can you describe that briefly?

11 A Yes.

12 I worked with Janssen, as an employee of  
13 Parexel, on one of their pain products. It's a  
14 patch -- pain patch used to treat acute  
15 postoperative pain, and I believe I provided some  
16 consultation for a drug called Risperdal.

17 Q And ultimately, you said you went to work  
18 for Janssen --

19 MR. DUCK: Objection to form.

20 Q -- is that correct?

21 A That's correct.

22 Q When was that?

23 A I, I started at Janssen in October of 2000.

24 Q And why did you go to Janssen?

25 A I was very interested -- I had an

1 opportunity to really see how a number of  
2 pharmaceutical companies engage in their clinical  
3 trials and how they are run. And I was very  
4 impressed with the way Janssen worked, the type  
5 of -- how they did what they did, and I was  
6 interested in their products.

7 Q Did you continue to work on pain products  
8 while at Janssen?

9 A I did. While at Janssen, during my time --  
10 and this -- for my 16 years, I worked on three pain  
11 products, as I testified; Duragesic, tramadol, and  
12 tapentadol.

13 Q Were any of those Schedule II opioid  
14 products?

15 A Yes. Two of those were Schedule II:  
16 Duragesic, the transdermal fentanyl patch; and  
17 tapentadol.

18 Q And was there a brand name for tapentadol?

19 A Yes. So, tapentadol has two formulations.  
20 It's an immediate-release and an extended-release.  
21 The immediate release of tapentadol is called  
22 Nucynta. But for purposes of conversation, we may  
23 call it Nucynta IR, but it's actually just called  
24 Nucynta. And an extended release of tapentadol,  
25 called Nucynta ER, for extended release.

1 Q Were any of those products already on the  
2 market as approved drugs when you started at  
3 Janssen?

4 MR. DUCK: Objection to form.

5 A Duragesic was on the market, but tapentadol  
6 was not on the market.

7 Q What position did you hold at Janssen?

8 A So, when I first started at Janssen, I was  
9 a medical director. And as I testified earlier,  
10 after several years, I was promoted to a senior  
11 medical director.

12 Q And who did you work with there?

13 A I worked with Dr. Bruce Moskovitz.

14 Q What was his position?

15 A He was the leader of the analgesia group.  
16 Analgesia was, at one point, called analgesia  
17 mycology. There was a substance used to treat my --  
18 mycol -- mycology infectious, but it was mostly  
19 analgesia.

20 And he was the group leader. He had  
21 different titles over the years, but that's what his  
22 role was.

23 Q And what is analgesia?

24 MR. DUCK: Charlie, every single question  
25 you've asked has already been covered. I'm

1       trying to give you some leeway. I mean, I want  
2       you to be able to cover what I covered. We're  
3       paying for this deposition; we're paying for  
4       the pages. And literally every question has  
5       already been covered.

6           MR. LIFLAND: This is background.

7           MR. DUCK: Let me ask you this: Are you  
8       intending to offer him as an expert in this  
9       case? Because this is not the expert  
10      deposition, if you are.

11          MR. LIFLAND: We haven't reached that point  
12      yet. But right now, I'm asking him about facts  
13      that he knows from his work at Janssen.

14          MR. DUCK: My question is why, so I can  
15      know whether or not to object, to file a  
16      motion, or whatever else.

17          MR. LIFLAND: This is not an expert  
18      deposition. This is a fact deposition.

19          MR. DUCK: Okay. Well, can you move on to  
20      something that has something to do with the  
21      testimony that hasn't already been covered that  
22      you want to cover?

23          MR. LIFLAND: This is a direct examination.  
24      I can ask whatever I want.

25          MR. DUCK: But why? It's useless.

1 MR. LIFLAND: I don't, I don't -- it will  
2 take less time if we don't debate this and let  
3 me just get through my examination.

4 Q What were your responsibilities as a  
5 medical director?

6 A So, my responsibilities as a medical  
7 director in the U.S. medical affairs group was, I  
8 was responsible for clinical trial work. I was  
9 responsible for working on analyzing data that came  
10 in from clinical trials, developing protocols for  
11 clinical trials, and working with other individuals  
12 in the company, working with the outcomes research  
13 group, working, again, with the safety group,  
14 working, as well, to -- and I also indicated that I  
15 had worked to set up the acute surveillance program  
16 for our opioid analgesics.

17 Q All right. Can you describe your  
18 involvement in safety monitoring?

19 MR. DUCK: Objection to form.

20 A So, I was -- because of my expertise and  
21 background as an anesthesiologist, I was asked  
22 periodically to review data that came in, safety  
23 data from the safety group.

24 And in addition to that, as I've already  
25 indicated, I developed acute surveillance

1 methodologies, using both RADARS and Inflexxion  
2 data, to monitor our opioid analgesics.

3 Q And which opioid analgesics are you talking  
4 about?

5 MR. DUCK: Objection to form.

6 A So, we initially had been -- started  
7 monitoring Duragesic, the transdermal fentanyl  
8 patch.

9 Tramadol was eventually brought over as  
10 part of the monitoring.

11 And then, when tapentadol came to the  
12 market, tapentadol was included in the monitoring,  
13 as well.

14 Q Let's start with Duragesic.

15 What is Duragesic?

16 MR. DUCK: Objection to form.

17 A Duragesic is a transdermal fentanyl  
18 product. It contains pharmaceutical-grade fentanyl  
19 in a patch. The patch is applied to the skin. The  
20 fentanyl medication, the pain medication, goes  
21 across the skin and into the body to provide pain  
22 control.

23 Q How long has Duragesic been on the market?

24 MR. DUCK: Objection to form.

25 A I believe Duragesic first came to the U.S.



1 market in 1990.

2 MR. DUCK: Charlie, can I have a running  
3 objection to your entire direct examination?

4 MR. LIFLAND: No, you can object.

5 MR. DUCK: Okay. I'll object every time.

6 BY MR. LIFLAND:

7 Q Have you heard of illegally manufactured  
8 street fentanyl?

9 MR. DUCK: Objection to form.

10 A Yes, I have.

11 Q Can you explain what that is?

12 MR. DUCK: Objection to form.

13 A Yes. So, in contrast to  
14 pharmaceutical-grade fentanyl, which is produced  
15 under highly regulated requirements and is very  
16 pure, the illegal heroin is not produced in a, in a  
17 way that's regulated at all; so that, with a patch,  
18 such as Duragesic, a known amount of this  
19 pharmaceutical-grade fentanyl diffuses across the  
20 skin to treat a patient's pain.

21 Illegal fentanyl is made differently and  
22 may have other substances, as well, and it's not  
23 controlled, and has impurity.

24 MR. LIFLAND: If you really are going to  
25 object to every question, I think I will

1 rethink that and give you a running objection.

2 MR. DUCK: Thank you. So, just so we're  
3 clear, I have got a running objection to your  
4 direct examination --

5 MR. LIFLAND: No. To the form of my  
6 questions. That's the only objection I'm  
7 giving you.

8 MR. DUCK: That's what I will be objecting  
9 to anyway. So, form objections are preserved  
10 during your direct examination --

11 MR. LIFLAND: Yes.

12 MR. DUCK: -- is that right?

13 MR. LIFLAND: Yes.

14 MR. DUCK: Okay, thanks.

15 Q Does the illegal fentanyl have anything to  
16 do with Duragesic?

17 A It did not.

18 Q Which patients is Duragesic intended for?

19 A So, Duragesic is a medication used to treat  
20 chronic pain. So, it's used -- and I'm paraphrasing  
21 from the product label. It's used -- it's, it's  
22 approved for the use in patients with chronic pain,  
23 where an opioid analgesic is required around the  
24 clock for an extended period of time for the  
25 treatment of pain severe enough to require an

1 opioid, where lesser forms of pain medications are  
2 not -- you know, are not appropriate for treating  
3 the patients -- were not able to treat the patients.

4 Q Can patients be started on Duragesic as a  
5 first-line treatment?

6 A No, they cannot. Patients who are not  
7 opioid-tolerant -- patients who are not  
8 opioid-tolerant -- that is to say, for opioid-naive  
9 patients, Duragesic is contraindicated. They need  
10 to be on a certain amount of opioid analgesics  
11 before starting Duragesic.

12 Q Is use of Duragesic limited to any  
13 particular kind of chronic pain?

14 A No, it's not. Duragesic may be used to  
15 treat any kind of chronic pain, regardless of  
16 ideology, as long as it fits the criteria in terms  
17 of the severity and the requirement for opioid  
18 analgesia, as I've already discussed.

19 Q What kinds of chronic pain?

20 A So, it can be used to treat chronic pain  
21 associated with cancer, it can be associated with --  
22 chronic pain associated with low back pain, and  
23 other types of chronic pain, as well.

24 Q Has Duragesic always been approved for  
25 chronic pain?

1 A Yes, it has been.

2 Q Is Duragesic approved for pain that is not  
3 chronic?

4 A No, it is not. It's only approved for  
5 chronic pain. In fact, I think it's contraindicated  
6 for acute pain.

7 Q What are the benefits of Duragesic for the  
8 patient?

9 A As a patch technology, there are certain --  
10 there are several benefits. One, patients don't  
11 need to take a pill. It's a patch that's applied to  
12 the skin. And Duragesic delivers  
13 pharmaceutical-grade fentanyl in a known -- in a  
14 known dosing, and in a known quantity. And it's --  
15 after a steady state is achieved, the medication  
16 is -- for most patients, is -- lasts for 72 hours.  
17 We know that, for some patients, the medication only  
18 lasts for 48 hours. And our product label states  
19 that accordingly.

20 Q Does the design of the patch make abuse  
21 more difficult?

22 A Yes. In my opinion, and the opinion of  
23 others, as well, the design of the patch is such,  
24 that we talked about, the pharmaceutical-grade  
25 fentanyl diffuses across the skin, goes into the

1 body.

2 But the rate of rise -- that is the time it  
3 takes for the fentanyl to get to the central nervous  
4 system -- is slower than what would be desirable by  
5 people who would want to abuse or who are addicted  
6 to opioid analgesics, where they want a very quick  
7 high. So, for addicts or people who abuse the  
8 medication -- intravenous medication or snorting it  
9 would be two examples to do that. Because Duragesic  
10 is delivered in a slower fashion over a period of  
11 time, when we talked about the rate of rise in the  
12 central nervous system, it would tend not to be as  
13 desirable. That's one reason.

14 The second reason is that fentanyl, in the  
15 gel, is mixed with other, with other ingredients,  
16 other excipients; so that, if addicts would try and  
17 inject this, for example, not only would they get  
18 the fentanyl, but they would get these other med --  
19 these incipient products, as well. And those can --  
20 injecting Duragesic can be very, very dangerous, the  
21 gel from the patch.

22 Q And how does that affect abuse?

23 A Well, if addict -- we -- early on, when the  
24 product was on the market, we became aware of the  
25 fact that addicts were trying to extract the gel and

1 inject it intravenously.

2 And what we learned, unfortunately, that  
3 those patients, when they did that, if they used it  
4 inappropriately, tampered with it -- and these were  
5 addicts, not patients -- chronic pain patients --  
6 that those patients, unfortunately, got quite sick  
7 and some of them died.

8 We know from our Internet monitoring  
9 activities that took place, when we started  
10 monitoring the Internet, there were warnings by  
11 addicts that the patch system was dangerous and they  
12 should stay away, because of the reports that they  
13 had of what I just described to you, people who  
14 tried to get at the gel and inject it, to shoot it,  
15 mainline it, and the patients were -- sorry, the  
16 addicts were quite sick, and many of these people  
17 died. These people didn't just die. There weren't  
18 many, but there were some deaths.

19 Q Is there still a potential for abuse of  
20 Duragesic?

21 A Yes. Any opioid can be abused. And  
22 Duragesic can be abused, as well.

23 Q Is Duragesic scheduled?

24 A Yes, it is. Duragesic is a controlled  
25 substance. It's a Schedule II.

1 Q And is the abuse potential described in the  
2 labeling?

3 A Yes, it is. The product labeling does  
4 mention that it is a C2. And the schedule C2 is  
5 defined in law for bio abuse potential, as the  
6 highest level of scheduling.

7 MR. LIFLAND: What exhibit number are we up  
8 to?

9 MR. DUCK: Fifteen, I think.

10 Q So, I've handed you a document that I've  
11 marked as Exhibit 15.

12 I need a sticker to actually do that.

13 MR. DUCK: Is there some way to denote  
14 whether it was your exhibit or my exhibit? I  
15 mean, if you want to write something else on  
16 these to denote that, I would appreciate it.

17 MR. LIFLAND: We haven't been doing that in  
18 any of the other depositions. We've just been  
19 numbering them.

20 MR. DUCK: It's my deposition, though. So,  
21 if you'll put "Defendant's Exhibit" or write a  
22 "D" on it, I'd appreciate it.

23 MR. LIFLAND: Well, let's -- we can do that  
24 afterward. Let's just -- we're going to call  
25 it Vorsanger 15 for this purpose.

1 MR. DUCK: To the extent, you know, it's  
2 unclear in the record, these are not the  
3 State's exhibits, starting with Exhibit 15  
4 onward.

5 (Highlights of Prescribing  
6 Information was marked as  
7 Vorsanger 15 for identification,  
8 as of this date.)

9 Q I've just handed you, Dr. Vorsanger, what I  
10 marked as Exhibit 15.

11 Can you identify that document?

12 A Yes. This is the full prescribing  
13 information for Duragesic, also known as the package  
14 insert for the product.

15 Q And does this package insert provide  
16 information about the potential for abuse of the  
17 product?

18 A Yes, it does. As a matter of fact, in the  
19 black box warning, it talks very specifically in the  
20 first bullet: "Duragesic exposes users to risks of  
21 addiction, abuse, and misuse, which can lead to  
22 overdose and death."

23 Q Does the insert then go on to describe  
24 those risks?

25 A Yes, it does. As you go through the



1 package insert, there is a black box warning which  
2 is described. And as you go through further and  
3 look in the package insert -- and the package insert  
4 is information that prescribers use to learn about  
5 the products and how to use it safe and effectively.

6 And if you go -- it talks about section  
7 5.1, under "Warning and Precautions," where it  
8 specifically discusses addiction, abuse, and misuse.

9 Q And you've mentioned that it gives  
10 information about how to use the product safely and  
11 effectively.

12 A Yes.

13 Q Let me ask you to identify the parts of the  
14 label where that's discussed.

15 A Absolutely.

16 So, if you look -- as you go through the  
17 label, the indications and usage are in section 1.

18 Dosing administration provides the --  
19 provides information to the healthcare provider on  
20 how to dose, how to titrate and maintain therapy,  
21 and what dosage modifications may be needed,  
22 depending on the patient's medical history.

23 So, for example, "Dosage Modifications in  
24 Patients with Hepatic," that's liver impairment; or  
25 "Patients with Renal," that's kidney impairment.

1 And it goes on.

2 It talks about dosage forms and strengths,  
3 which ones are available.

4 It talks about the contraindications, where  
5 the drugs should not be used.

6 And then at section 5 is "Warning and  
7 Precautions," and we talked a little bit about on --  
8 "Addiction, Abuse, and Misuse" is 1.

9 It goes on to talk about its effect and how  
10 it can compete with other medications and how the  
11 body breaks down drugs, how to think about it if  
12 patients have head injury, with increased pressure  
13 in the -- on the brain because of that.

14 It has extensive experience -- discussions  
15 about adverse events and talk -- in section 6, and  
16 talks about clinical trial experience and about the  
17 company's post-marketing experience.

18 And then "Use in Specific Populations."

19 "Drug Interactions," in 7. What to think  
20 about as you -- if you talk your -- as you talk to  
21 patients about drugs, what -- you need to find out  
22 what medications they're on. We talked about taking  
23 a history earlier today and finding out what other  
24 drugs are.

25 And then section 8 uses it -- how it's used

1 in specific populations; women who might be  
2 pregnant, breast feeding, and then for geriatric  
3 patients, et cetera.

4 Section 9 goes through drug abuse and  
5 dependence.

6 And then section 10 talks about potential  
7 overdose and goes on, in addition, to talk about the  
8 clinical pharmacology.

9 So, the document really covers -- for me,  
10 as a clinician, and when I read this and think about  
11 it, quite a lot of information on how to use the  
12 product safely and effectively and how to understand  
13 how the product can be used in various patient  
14 populations.

15 Q Can you turn to page 12 of the document.

16 A Yes.

17 Q Can you -- you see the section 5.1,  
18 entitled "Addiction, Abuse, and Misuse"?

19 A I do.

20 Q Can you read what information is given to  
21 doctors in the second and third paragraph of that  
22 section on those subjects.

23 A Yes.

24 For the second paragraph, it says,  
25 "Although the risk of addiction in any individual is

1 unknown, it can occur in patients appropriately  
2 prescribed Duragesic. Addiction can occur at  
3 recommended doses and if the drug is misused or  
4 abused."

5 And underneath that, it says, "Assess each  
6 patient's risk for opioid addiction, abuse, or  
7 misuse prior to prescribing Duragesic, and monitor  
8 all patients receiving Duragesic for the development  
9 of these behaviors and conditions. Risks are  
10 increased in patients with a personal or family  
11 history of substance abuse (including drug or  
12 alcohol abuse or addiction) or mental illness," and  
13 the example they gave here is "major depression."  
14 "The potential of these risks should not, however,  
15 prevent the proper management of pain in any given  
16 patient."

17 Q Can you just continue, just to the end of  
18 that paragraph?

19 A Sure. Yes.

20 "Patients at increased risk may be  
21 prescribed opioids such as Duragesic, but use in  
22 such patients necessitates intensive counseling  
23 about the risks and proper use of Duragesic along  
24 with intensive monitoring for signs of addiction,  
25 abuse, and misuse."

1 Q And this package insert, do you know  
2 whether it undergoes a regulatory process?

3 A It does. So, when a product is first  
4 approved, the package insert is created by  
5 discussion with FDA, based on the available data,  
6 and the package insert is updated periodically, as  
7 new safety information or other type of information  
8 that FDA and/or the company deems is important to  
9 put in there to inform both healthcare providers and  
10 patients, as well.

11 Q So, this is an FDA-approved information  
12 that's provided?

13 A Yes. This is an FDA-approved document.

14 Q Can you describe how Janssen monitors the  
15 potential and actual abuse and misuse of Duragesic  
16 in the real world?

17 A Yes. So, monitoring for abuse occurs in  
18 two -- on two -- in two ways:

19 One, there is monitoring using systems of  
20 passive surveillance, and we talked a little bit  
21 about that. They're not really passive, they're  
22 getting data that come into the company either  
23 through phone calls or through reports that come in  
24 from healthcare providers and/or from patients.

25 They also -- databases are looked at. So,

1 Janssen maintains a database of all the adverse  
2 events of all of its medications.

3 Janssen also reviews an FDA database for  
4 adverse events. That FDA database is called AERS,  
5 the Janssen database is called SCEPTRE. We talked a  
6 little bit about that earlier. And those are the  
7 ways that the data are analyzed to look for all  
8 adverse events, including abuse, misuse, and  
9 addiction.

10 Q What geography does SCEPTRE cover?

11 A SCEPTRE covers the entire world. So,  
12 reports that we have coming in from around the world  
13 for use of the product are reported in SCEPTRE. The  
14 information is processed by people with expertise to  
15 look at those type of work. Reports are compiled.  
16 The adverse events are analyzed, reports are made,  
17 and that information is submitted to FDA.

18 In addition, we have an active surveillance  
19 program, that I had already testified that I set up  
20 when I was at Janssen, that used information both  
21 from RADARS and later from Inflexxion, and used  
22 other databases, as well.

23 Q What --

24 A And that --

25 Q I'm sorry.

1           A     And that information was -- and I set those  
2 programs up specifically because it took time for  
3 the passive surveillance, for the information to  
4 come in, to be looked at, to be analyzed, and I  
5 wanted more real-world -- real-world, real-time  
6 information coming in.

7                     So, not only did I use RADARS and  
8 Inflexxion, that I had testified this morning, but I  
9 also set up a program of media monitoring, where I  
10 had individuals looking at the lay press to see for  
11 mentions of our products.

12                    The pharmacovigilance group looks at  
13 scientific articles, but the lay press wasn't looked  
14 at, and now it is. They may have looked at some of  
15 the lay press, but I had a formal way that I looked  
16 at it.

17                    In addition, as I also testified, we set up  
18 Internet monitoring to look not only at current  
19 trends for how the product might be abused, but if  
20 there was a change in those trends.

21           Q     Now, what's the overall purpose of looking  
22 at all of these streams of information?

23           A     To understand the rates of abuse, and are  
24 those changing with time, methods of abuse, are  
25 those changing; so, that we can ensure that we can

1 inform not only the health regulatory authorities,  
2 but also healthcare providers, on how the product  
3 might be abused and if there are changes in the  
4 abuse patterns.

5 (JAN-MS-02321524 was marked as  
6 Vorsanger 16 for identification,  
7 as of this date.)

8 Q I've handed you an exhibit that I've marked  
9 as Vorsanger Exhibit 16.

10 Can you identify that document?

11 A Yes. The document says "Risk Management  
12 Plan for Our Products," and it's dated May 9, 2005.

13 Q And is that a document that you created?

14 A This is a document that I either created or  
15 provided the information that went into the  
16 document.

17 Q So, this describes the risk management plan  
18 for Duragesic that you were just describing in your  
19 prior answer?

20 A That's correct, yes.

21 Q Will you turn to the second slide.

22 A Yes.

23 Q Does this accurately describe why Janssen  
24 created this Risk Management Strategy?

25 A Yes, it does.



1           So, the first item says, "Why create an  
2 RMP?" or risk management plan. This is the strategy  
3 behind it, because what we believe at the company,  
4 and believed at the company, is it's the right thing  
5 to do. We are marketing products that have a known  
6 abuse potential, and we want to understand the  
7 mentions of abuse, rates of abuse, and, again, if  
8 there is a change in the abuse pattern, that we're  
9 appropriately labeled for it, and that our  
10 educational programs inform people who care for, not  
11 only for patients, but are aware of the fact that  
12 people who may seek to abuse the product, that  
13 they're aware of that, as well.

14           The second bullet, it ultimately became  
15 required by FDA.

16           And those are some of the main reasons we  
17 have.

18           Q     Can you turn to page 11, slide 11.

19           A     Sure.

20           Q     Can you describe what this slide is  
21 depicting?

22           A     So, when I put the program together, one of  
23 the things that I was thinking about would be who  
24 would be the individuals who would need to be part  
25 of a risk management program to actively survey our

1 products?

2           So, if you look at the categories on the  
3 top, we want to have individuals who are  
4 knowledgeable about product labeling, for the  
5 reasons I just spoke about; that if we needed to  
6 change the label for any reason, they were in a  
7 position to help with that.

8           We wanted to make sure that education was  
9 represented, as I've already testified, on what may  
10 or may not need to be changed.

11           We wanted to ensure that our launch  
12 promotion activities were robust, that they captured  
13 what we knew about the product and most up-to-date  
14 information about safe and effective use of the  
15 product.

16           The individuals who are responsible for the  
17 product, including regulatory affairs, medical  
18 affairs, representation from the research and  
19 development group -- we had a representative from  
20 our legal group. The med affairs was responsible  
21 for the active surveillance, as I've testified. The  
22 passive surveillance program was from our  
23 pharmacovigilance group. And we had people who sat  
24 on this risk management team, from our supply chain  
25 group, to inform really the other people in the

1 organization who handled the product who were  
2 responsible for the product, if there were any  
3 issues that came up around the diversion.

4 Q What was the external advisory board that's  
5 referred to here, in the box under "Review with  
6 independent external advisory board"?

7 A Right. So, when I put this together, the  
8 group of individuals on the risk management team  
9 were fairly straightforward for me. As I mentioned,  
10 these are the people that worked with the drug every  
11 day at the company.

12 I wanted to make sure that we weren't  
13 siloed and that we had external expertise from  
14 people who could help us with safety issues, if  
15 those arose, and to provide guidance to us.

16 So, I assembled people with knowledgeable  
17 backgrounds from a number of different areas, and I  
18 met with them or other members of the company had  
19 met with them to talk about potential safety issues  
20 and to share some of the data that we had observed  
21 from RADARS, at that point in time, to get their  
22 feedback and opinion.

23 Q Can you tell me who were the members of  
24 that external review committee?

25 A Yes. So, we wanted an individual who was

1 knowledgeable in FDA requirements and product  
2 labeling. So, Cynthia McCormick, at that time, had  
3 led the FDA. And I had reached out to her. She was  
4 interested in this committee. So, she was our FDA  
5 representative on the external review committee.

6 I also wanted somebody from DEA who was  
7 knowledgeable about DEA processes and et cetera.  
8 So, I reached out and contacted Mr. Frank Sapienza,  
9 and he also joined in and provided DEA perspective,  
10 as we talked about our opioid medications.

11 I wanted someone with expertise in pain  
12 management, a physician who was an expert in pain  
13 management, who also knew our products well. And  
14 so, Dr. James Otis, up in Boston, who prescribes  
15 Duragesic for -- or prescribed Duragesic for his  
16 patients, was a member of the committee, as well.

17 I also felt it was important to have  
18 someone who could provide us with an ethical  
19 perspective. We certainly had the credo as the  
20 guiding principles for our ethics, but I wanted  
21 somebody outside the company who could kind of look  
22 in and help us with this. So, Art Caplan was  
23 someone who was an ethicist, well-known. I reached  
24 out to him, and he sat on the committee, as well.

25 And then lastly, since active surveillance

1 was a new methodology for me, I didn't have a lot of  
2 experience with it, I wanted to have someone with  
3 expertise in signal detection methodology. So,  
4 Annette Stemhagen, who is someone who has expertise  
5 from that, joined it, as well.

6 And I met quarterly with the external  
7 review committee. We discussed issues that came up.  
8 Some of what we might be thinking about, if a  
9 potential safety issue did arise, that was something  
10 that we could discuss with them to get their input  
11 and their feedback.

12 MR. LIFLAND: Let's get the next document.

13 A Are you done with this?

14 Q Yeah.

15 (JAN-MS-02305132 was marked as  
16 Vorsanger 17 for identification,  
17 as of this date.)

18 MR. DUCK: Thank you.

19 Q There you go. I just handed you what I've  
20 marked as Exhibit 17.

21 Have you seen that document before?

22 A Yes, I have.

23 Q And can you describe what it is?

24 A So, the title of the document is "Risk  
25 Management Overview," a presentation that was put

1 together by the person who was my supervisor at the  
2 time, Dr. Bruce Moskovitz.

3 Ortho-McNeil Janssen Scientific Affairs was  
4 another product company that went on to become part  
5 of J&J -- or Janssen, I'm sorry. It was a J&J  
6 company, it became part of Janssen.

7 And the date of the presentation was 20th  
8 of April 2007.

9 Q And what does the presentation describe?

10 A So, it starts with a discussion of the drug  
11 safety landscape and how FDA reviews it and provides  
12 guidance.

13 Q Well, let me just -- I didn't mean to have  
14 you go through everything.

15 Just in high level, what is this slide deck  
16 about?

17 A So, this is about risk management, risk  
18 management guidance, the goals of setting up a risk  
19 management program, the types of interventions that  
20 need to have [sic], and the tools that were needed  
21 on what we need to develop to use -- to develop this  
22 type of a program.

23 Q And if you turn about, I want to say, a  
24 third of the way in, you'll see that there's a slide  
25 that's entitled "Duragesic Risk Management Plan."

1 Do you see that?

2 A Yes.

3 Q And does that refer to the same plan that  
4 we were discussing in the prior questions about the  
5 last exhibit?

6 A Yes. It talks about, on the next page, the  
7 risk management strategy, how you stratify risks,  
8 how you address risks and look at data to understand  
9 it, how you manage it and assess it.

10 And underneath it, the boxes entitled  
11 "Labeling, Education, Launch/Promotion,  
12 Surveillance," et cetera, come directly from the  
13 risk management team and the risk management program  
14 that I had set up for the -- with the company.

15 Q Let's turn to the slides that describe the  
16 elements of the surveillance plan. If you keep  
17 going, you'll see there's a slide on internal review  
18 committee and external review committee.

19 A Right.

20 Q Those are the two committees that you  
21 described in your prior answer?

22 A Right. So, I didn't talk about the  
23 internal review committee yet, which I'm happy to do  
24 now.

25 Q Okay.

1           A       The external -- let me spend a moment on  
2       the product risk management team, before I get to  
3       the other -- just to briefly touch about -- on it.

4                   Remember, I said the people who are  
5       responsible for the compound at the company -- so,  
6       there's someone from medical affairs. I was the  
7       chairperson for it. There was somebody from our  
8       safety group, regulatory affairs, medical affairs,  
9       from R&D. We had somebody from marketing, as well,  
10      and from some of our global groups. And our ad hoc,  
11      as needed, was -- we had legal, we had J&J's  
12      security, and other groups, as well.

13                  Now, to talk about -- let me find the slide  
14      for the internal review committee that you were  
15      asking me about. Okay, I have it.

16                  So, all of the people that were on the risk  
17      management team and that were part of it, the people  
18      whom they reported into, the vice president-level  
19      individuals, were part of the internal review  
20      committee. So, this was senior management at the  
21      company.

22                  And as you can see, it says, "Membership  
23      (functional senior management)." And these  
24      categories correspond to the people that were  
25      actually in it.



1           And on the right side, it talks about the  
2     responsibilities of this. This was a  
3     decision-making body. So, after the risk management  
4     team -- and I've described that already -- comes up  
5     and reviews the available data, they will make  
6     recommendations to the internal review committee,  
7     which essentially are a lot of their supervisors or  
8     maybe even a level above their supervisors. This  
9     team will then review the data, review the  
10    suggestions made by the product risk management  
11    team, and make certain types of recommendations.

12           If we also feel that we need help from the  
13    external review committee -- and I discussed the  
14    external review committee already, and who was on  
15    that -- then the data could be shared not only --  
16    would be shared not only with that, but could be  
17    shared certainly with the external review  
18    committees, as well.

19           Q     And there is a next -- there's another  
20    slide that references the external review committee.

21                   That's the same committee that you already  
22    described the membership of?

23           A     Precisely, yes.

24           Q     Turn to the next slide after that.

25           A     Which one is that?

1 Q It's --

2 A Passive surveillance?

3 Q Passive surveillance, yes.

4 A Okay. Did I go past it?

5 Q You went past it. You went past it.

6 A Oh, okay. I'll go back. Is it the other  
7 way?

8 Q Yeah, I think it is the other way.  
9 External review committee, and then you go two  
10 slides.

11 A Here it is. Okay, great.

12 Okay. So, the passive surveillance --

13 Q Let me ask you a question, first.

14 A Sure, sorry.

15 Q I'm sorry to keep it in the  
16 question-and-answer format.

17 Can you describe what this slide depicts?

18 A Yes. So, this, this slide discusses the  
19 passive surveillance and some of the databases that  
20 are used.

21 We already talked about information coming  
22 in from adverse events, but other data that were  
23 looked at as part of the passive surveillance  
24 methodologies -- the databases were DAWN, and we  
25 talked about that; the Toxic Exposure Surveillance

1 system, TESS, which I think was a forerunner of the  
2 Poison, U.S. Poison Control Network; National  
3 Forensic Laboratory Information System, the NFLIS;  
4 and another database called Intercontinental  
5 Marketing Services, IMS; so, the Health LRx  
6 database, looking at prescriptions.

7 Q And just briefly, what was DAWN?

8 A So, DAWN, it was a network that looked at  
9 individuals presenting to emergency rooms with, with  
10 overdose or -- from opioid analgesics.

11 Q And you mentioned TESS was poison control?

12 A I believe that was a forerunner for the  
13 U.S. Poison Control Network.

14 Q And NFLIS -- it says "forensic  
15 laboratory" -- what kind of information would be  
16 retrieved from that?

17 A So, my recollection was that the NFLIS had  
18 information from forensic -- things that came about  
19 as far as law enforcement activities, where  
20 medications may have been seized or they became --  
21 medications at crime scenes or something like that,  
22 to see what drugs were.

23 Q And how about IMS?

24 A IMS is -- the IMS database was looking at  
25 prescriptions, and I guess to be able to use

1 demographics on who was using the drug -- who was  
2 being prescribed the drug, how, and et cetera,  
3 dosing, et cetera.

4 Q If you look at the next slide, there is a  
5 table that, again, refers to "Passive Surveillance:  
6 Monitoring Activities by Risk."

7 Can you explain what that slide is  
8 depicting?

9 A Yes. So, the slide says "Passive  
10 Surveillance: Monitoring Activities by Risk." It  
11 talks about the type of risk. And the risks that  
12 are listed in the table are "Abuse, Overdose,  
13 Misuse, Diversion," and on the bottom is "Other  
14 Adverse Events of Interest." And then looks at the  
15 various passive surveillance methodologies to look  
16 at these various adverse events.

17 So, the J&J database, which we discussed is  
18 SCEPTRE, looks at all of them. The FDA AERS  
19 database, which we discussed, also looks at all of  
20 them. So, both look at abuse, overdose, misuse,  
21 diversion, and other AEs of interest.

22 TESS, we talked about, looks at abuse,  
23 overdose, and misuse.

24 The NFLIS looks at diversion.

25 The IMS LRx looks at misuse.

1           And the DAWN data looks at abuse and  
2 overdose.

3           Q     If you turn to the next slide, entitled  
4 "Active Surveillance."

5           A     Okay.

6           Q     What is active surveillance?

7           A     So, as I had testified, active surveillance  
8 was a system that I worked with the company to put  
9 in place to get more real-time or more information  
10 that could come in more quickly to the company for  
11 us to be able to act on if we became aware of  
12 issues.

13                 So, we have discussed RADARS. That was one  
14 of the sources of data that came in for analysis.

15           Q     And that had several components, I take it?

16           A     It did.

17           Q     And we can discuss those -- we'll get to  
18 those, but could you explain what the media  
19 monitoring and Internet monitoring were, before we  
20 do that?

21           A     Yes. So, media monitoring was monitoring  
22 for the lay press for potential mentions of  
23 Duragesic. And it would help us with trends or  
24 reasons which people might be describing either  
25 abusing it or what might be going on.

1           And Internet monitoring, in the 2005  
2     timeframe, which would be about 10 years, I guess,  
3     from when the Internet became more widely available  
4     in 1995 -- we thought it would be important to see  
5     whether addicts were talking about how they might be  
6     abusing our product. And, in fact, they were.

7           And Pinney Associates, which is a company  
8     that has expertise in abuse, did the Internet  
9     monitoring for us, went to the websites that addicts  
10    go to, to understand how our product may be abused,  
11    the methodologies, and whether there were  
12    conversations about how it would be used [sic], with  
13    the purpose of understanding what addicts thought  
14    about our drug, and if there were changes, as we  
15    talked about earlier today, in patterns of abuse  
16    that could occur, we would be able to detect that,  
17    and, again, inform through our education and other  
18    places, to be able to do that.

19       Q     Can you turn to the next slide and explain  
20     what that slide is depicting?

21       A     So, this slide says, "Active Surveillance:  
22     RADARS," and it talks about the RADARS networks that  
23     we had, that I worked on when I was there, and there  
24     were four.

25           There was the Key Informant Network, the

1 Law Enforcement Network, the American Association  
2 for the Treatment of Opioid Dependence -- and that's  
3 called AATOD -- and the Poison Control Network.

4 Q What was the Key Informant Network?

5 A So, the Key Informant Network, I believe,  
6 was a network that is run by Dr. Cicero, and I  
7 believe these are surveys that go out to individuals  
8 who work with people who would abuse opioid  
9 medications or are addicted to them, to inform us on  
10 the various medications that those people use, and  
11 to have an idea about how much they use and how  
12 they're used.

13 Q What's the Law Enforcement Network?

14 A The Law Enforcement Network was a network  
15 that was run formerly by Dr. James Inciardi. It was  
16 taken over by his wife, I believe, after he passed  
17 away. And that got information from individuals in  
18 law enforcement who may have been associated with  
19 either -- and I'm not sure specifically exactly  
20 where they got the information -- these were surveys  
21 of law enforcement officials about what they had  
22 heard about our products, our product, about  
23 Duragesic, and ultimately the other products, as  
24 well, that got folded in.

25 Q And the Poison Control Network?

1           A     Poison Control was U.S. Poison Control.  
2     So, people either called, called in to have --  
3     wanted to talk about what issues were going on, if  
4     there was overdose or misuse or inappropriate use of  
5     our products, and that information would be  
6     collected by the U.S. Poison Control Network.

7           Q     Were there additional elements that came  
8     online with RADARS later on?

9           A     So, later on, RADARS made available a  
10    college survey, which was a survey of college  
11    students. I was particularly interested in that,  
12    along with the company, because this was a  
13    population of individuals who liked to experiment  
14    with these types of medications. And we wanted to  
15    understand whether our medications would be  
16    desirable to them.

17          Q     Let's take a look at the next slide.

18          A     Going the other way?

19          Q     Yeah. Just the first of these charts, the  
20    one that's entitled "Key Informant Data."

21          A     Okay.

22          Q     And can you explain what this chart is  
23    showing?

24          A     Yes. So, these are -- the slide is  
25    entitled "Key Informant Data: Average Number of



1 Cases by Drug and Responding Informant 2002 to  
2 2005."

3 And on the X axis, it has starting from the  
4 first quarter of 2002 through the first quarter of  
5 2005. On the Y axis is the average number of cases.  
6 And then on the bottom, it talks about buprenorphine  
7 cases, morphine, fentanyl, other oxycodone,  
8 hydrocodone cases, et cetera.

9 Q And so, what are these lines on the chart  
10 reporting?

11 A So, these are the average number of cases,  
12 and it's broken down by opioid.

13 Q Okay. Where does fentanyl appear?

14 A So, fentanyl is the green line. You can  
15 see, starting in 2002 -- again, Duragesic would have  
16 been on the market since 1990. Since 2002, it had  
17 been out for about 12 years. And it had fentanyl  
18 cases. But this is not only Duragesic. This might  
19 have been if there was illegal fentanyl and other  
20 things that contributed to fentanyl.

21 And what you can see with these data is  
22 that the line for fentanyl is low and remains  
23 consistently low through the timeframe of 2002 and  
24 2005.

25 These data are important, also, because

1 recall that I said Janssen didn't join RADARS until  
2 2005, 2006. But the data became available to us,  
3 because we wanted to understand what data had been  
4 collected by Purdue, as far -- as part of the data  
5 looking at these opioids. So, it gave us an  
6 opportunity for a snapshot in time, to go as far  
7 back as 2002 and provide this type of information to  
8 us.

9 Q Can you look at the next slide.

10 A Yes.

11 Q Can you describe what that depicts?

12 A Yes. So, this slide -- this slide is  
13 entitled "Law Enforcement Network Data: Drug  
14 Diversion Total Mentions 2002 to 2004." Again, this  
15 is from the Law Enforcement Network that I just  
16 talked about.

17 Q Where does fentanyl appear on that?

18 A So, fentanyl is the green line here, with  
19 the triangles. And here, what you can see, starting  
20 from the first quarter of '02 to the second quarter  
21 of '04 -- I'm not sure what the X axis is -- or the  
22 Y axis. The X axis is the dates I just gave you.

23 These are some of the compounds tracked by  
24 RADARS, not all opioids. And mentions of fentanyl  
25 remain fairly stable during that period from 2002 to

1 2004. They tend to be low compared to some of the  
2 other opioids that are here, and a stable pattern.

3 Q Can you take a look at the next slide.

4 A So, the --

5 Q Can you describe what this slide is  
6 predicting -- describing?

7 A Yes. So, the slide I'm looking at is  
8 called the "AATOD Report." These are individuals  
9 presenting with a history of drug addiction,  
10 seeking -- going to methadone maintenance programs,  
11 the drugs most commonly abused in prior month, and  
12 admission to the Methadone Maintenance Treatment  
13 Program, MMTP. The number here is, N is equal to a  
14 thousand, is 1,137. And it lists the highest, from  
15 the highest to the lowest of the reports by people  
16 presenting to these types of treatment programs.

17 Q And where does fentanyl appear in that  
18 estimate?

19 A So, fentanyl appears the third from the  
20 bottom. And it's amongst the lowest.

21 Q Can you turn to the slide -- I think it's  
22 two slides down, with the map of the United States  
23 on it, and explain what that slide is depicting?

24 A Yes. So, this slide is entitled the  
25 "RADARS System Poison Control Center Coverage."

1           At this time, when this deck was created,  
2       it said there were 38 poison centers serving over  
3       200 million Americans -- "people are currently  
4       enrolled or in paper stage -- paperwork stage." So,  
5       these centers may be coming up at that time.

6           Q     And if you go to the next slide, and  
7       explain that one.

8           A     In here, it says "PCC Data," Poison Control  
9       Center, "Data: Intentional Exposure Rates by  
10      Quarter for All Sites Combined."

11          Q     So, these are rates of what?

12          A     These are rates per hundred thousand  
13      population. So, the point was raised: What is the  
14      denominator? And the data now would have a  
15      denominator with the rates per hundred thousand  
16      population within the U.S.

17                And on the X axis, it's between -- it's the  
18      first quarter of '03 to the second quarter of '05.  
19      These are the opioid analgesics that are tracked by  
20      RADARS -- or were tracked by RADARS at that time.

21                Fentanyl is the green line with the  
22      triangle, and it's among the lowest opioids listed  
23      here from opioids that are tracked by RADARS, again,  
24      for the timeframe that we're talking about.

25          Q     And if you could turn just two more slides

1 down to the slide that's entitled "How well does the  
2 J&J RMP work?"

3 Do you see that one?

4 A I do.

5 Q Can you explain what that's describing?

6 A Yes. So, one of the questions that come up  
7 about risk management plans is, how effective are  
8 they, other than collecting data?

9 So, this slide depicts a story that took  
10 place by using the RADARS methodology. And it's  
11 entitled "How well does the J&J RMP work? The  
12 Fentanyl-Tainted Heroin Story."

13 So, we became aware of reports of heroin  
14 addicts dying of heroin containing fentanyl, in  
15 2006. I got a call from RADARS saying that there  
16 was this concern about fentanyl.

17 And because Duragesic patch that we talked  
18 about contains fentanyl, our question, which is on  
19 this slide here, is: "Was the fentanyl coming from  
20 the Duragesic patches?"

21 Our media monitoring, which we talked  
22 about, which monitors the lay press -- and we got a  
23 call from Poison Control that detected the signal at  
24 the initial outbreak -- and that people may recall,  
25 in '06, that some of the major cities in the United

1 States were first getting reports of this illegal  
2 fentanyl.

3 The company, in response to this,  
4 dispatched a former -- a person who formerly worked  
5 at DEA to investigate on our behalf, and learned  
6 that fentanyl was shown to be made from a  
7 clandestine laboratory in Mexico and was not part of  
8 the fentanyl that came from the Duragesic system.

9 So, here, in 2006, we already had a plan in  
10 place, we already had an awareness of this illegal  
11 fentanyl going on, and being tainted for the heroin  
12 in the United States. And we were able to identify  
13 that it was not our fentanyl that was part of that.

14 (JAN-MS-00151777 was marked as  
15 Vorsanger 18 for identification,  
16 as of this date.)

17 Q I'm going to hand you a document that I've  
18 marked as Vorsanger Exhibit 18.

19 Can you identify Exhibit 18?

20 A Yes. The document is entitled the "Fourth  
21 Risk Management Plan Progress Report" for Duragesic.

22 Q Is this a document that you've seen before?

23 A Yes. I was identified as one of the  
24 authors on the document.

25 Q So, this is a document that you were one of

1 the authors of --

2 A Yes, that's correct.

3 Q -- at the time this was prepared?

4 A That's correct.

5 Q And what is the document?

6 A This was information that was sent to FDA.  
7 It was put together by a multifunctional group, with  
8 individuals both from our pharmacovigilance group,  
9 as well as people from medical affairs, someone from  
10 our regulatory affairs group. We had somebody from  
11 a -- from our pharm -- from our marketing group and  
12 somebody from supply.

13 Q And it's entitled "Fourth Risk Management  
14 Plan Progress Report."

15 A That's correct.

16 Q Were there other progress reports?

17 A Yes, there would have been other ones  
18 before that. This is the fourth one, and there were  
19 other ones that would have predated this. This one  
20 is dated 16th June 2008.

21 Q And did they all follow, generally, this  
22 format?

23 A Yes, they did. The data that we had we  
24 would have included in those reports.

25 Q And can you confirm that -- I don't want to

1 spend a lot of time on it. It's a big document --  
2 that this document reports on the same elements that  
3 you just talked about from the presentation; the  
4 active surveillance, the passive surveillance?

5 A Yes.

6 Q Is that all reported on in this progress  
7 report?

8 A Yes. If you look at the table of contents,  
9 yes.

10 Q Now, over the years, the company prepared a  
11 number of these periodic reports on a regular basis?

12 A That's correct. These were reports that  
13 were required to be submitted to the FDA as part of  
14 the FDA processes.

15 Q And what did the company see in terms of  
16 safety signals, over the years, as the company  
17 tracked this information in the RFP for Duragesic?

18 A Right. So, for Duragesic, as I had  
19 testified earlier, we, we looked through both the  
20 active and surveillance using the methodologies for  
21 both. And we saw, in general, low mentions of abuse  
22 of Duragesic -- not zero, but low mentions of abuse.

23 Q Did the company ever review its  
24 pharmacovigilance data to look at the question of  
25 iatrogenic addiction?



1           A     Yes, it did. I believe the timeframe was  
2     2005 or thereabouts. The company was asked by, I  
3     believe, FDA, and possibly other regulatory  
4     authorities, to look at rates of iatrogenic  
5     addiction and did look at that for our products.

6                 We may have undertaken that, as well, on  
7     our own, but I think there may have been other  
8     interest, as well.

9           Q     I'm going to hand you a document I've  
10    marked as Vorsanger 19.

11                         (JAN-MS-02754767 THROUGH 783 was  
12                         marked as Vorsanger 19 for  
13                         identification, as of this  
14                         date.)

15          Q     Can you explain what this document is?

16          A     Yes. So, the document is entitled  
17     "Cumulative Review of Iatrogenic Addiction  
18     Associated with the Use of Transdermal Duragesic" --  
19     and in parentheses -- "(fentanyl) Patch." The date  
20     of the document is September the 6th, 2006. And I  
21     believe the document was prepared by our  
22     pharmacovigilance group.

23          Q     And this is a review of data from where?

24          A     This is a review of data worldwide for  
25     Duragesic. And I believe some of this methodology

1 was -- may have been requested by the FDA.

2 And again, as I mentioned, the products  
3 that were reviewed were the fentanyl matrix patch,  
4 which would have been used in Europe at this time;  
5 and the fentanyl reservoir patch, which was the  
6 Duragesic patch that we had been talking about.

7 Q And what were the events that were  
8 reviewed?

9 A So, what we looked at is the number of  
10 cases of confirmed addiction that took place, and we  
11 looked at that as a function.

12 And the denominator we looked at is the  
13 number of patient days. And that's the number of  
14 days that patients were actually on a transdermal  
15 fentanyl patch, either the matrix patch or the  
16 Duragesic patch.

17 The number of --

18 Q What period of time did that cover?

19 A Let me confirm what that is.

20 I believe that was from the time that  
21 product was first introduced into market until 2006,  
22 but let me just confirm that.

23 Yes. It's based on 596,725,348 patches of  
24 fentanyl sold or distributed from the time of launch  
25 through June 2005.

1 Q And what is the exposure in terms of  
2 patient days that that translates to?

3 A Right. So, I had talked about patient  
4 days. And the total exposure was 1,611,158,440.

5 Q And how many cases of addiction were found  
6 in that database over that period of time?

7 A 103 cases were identified.

8 Q And what was the conclusion of this review  
9 of addiction cases?

10 A So, for the 103 cases out of the total  
11 number, we have -- we are -- our conclusion was that  
12 the rates of -- the rate of iatrogenic addiction for  
13 the transdermal fentanyl patch was very rare, but  
14 I'll read the conclusion from the report.

15 "A review of 103 cases that reported drug  
16 dependence associated with chronic use of  
17 transdermal fentanyl patch indicates that the risk  
18 of iatrogenic addiction is very rare. The Company  
19 Court Data Sheet adequately communicates the risk  
20 associated with this product."

21 And the reason why we put this in is we  
22 were asked to see if our company core data sheet  
23 adequately reflected the information on iatrogenic  
24 addiction. And the report concluded that the  
25 information in the company, company core data sheet

1 was correct.

2 Q And are you aware of other literature that  
3 describes the rate of addiction in chronic pain  
4 patients for opioids more generally?

5 A So, there are two articles that I had  
6 reviewed that look at iatrogenic addiction. One was  
7 the study by Fishbain, and I believe it was 2008.  
8 And there was a Cochrane review looking at  
9 iatrogenic addiction -- Roger Choo [sic] I think is  
10 the senior author -- and I believe that was 2010.

11 Q I will mark as Exhibit 20 --

12 MR. DUCK: Did you mean Robert Chou --

13 Roger Chou, C-H-O-U?

14 THE WITNESS: C-H-O -- I believe it's -- I  
15 think -- is it Chou or Choo? See, I think it's  
16 C-H-O-U.

17 MR. DUCK: As long as we are talking about  
18 the same person.

19 THE WITNESS: I think -- yeah, it's Roger  
20 C-H-O-U. I think it's Chou.

21 (Review Article was marked as  
22 Vorsanger 20 for identification,  
23 as of this date.)

24 Q I'm placing before you an article I've  
25 marked as Exhibit 20.

1 Can you identify that?

2 A (No verbal response.)

3 Q Can you identify Exhibit 20?

4 A Oh, sorry.

5 Yes. This is a review article by Fishbain  
6 and colleagues entitled "What Percentage of Chronic  
7 Nonmalignant Pain Patients Exposed to Chronic Opioid  
8 Analgesic Therapy Develop Abuse/Addiction and/or  
9 Aberrant Drug-Related Behaviors? A Structured  
10 Evidence-Based Review."

11 Q What is a structured, evidence-based  
12 review?

13 A So, the nature of how the review is  
14 conducted that they looked at -- a number of  
15 articles -- they report 67 reports -- that they  
16 looked at a number of articles and determined the  
17 level of quality that they required to have in their  
18 reports to be able to come up and look at these to  
19 decide, again, what type of -- what a -- you know,  
20 what kind of rates of abuse and addiction are  
21 iatrogenic addiction.

22 And so, this was a structured approach  
23 about reviewing them, identifying the quality of  
24 evidence, the information that was in there, et  
25 cetera.

1 Q And what was the conclusion of the article?

2 A The conclusion that the authors came up  
3 with -- and I'm reading it, quote, from the article:  
4 "The results of this evidence-based structure review  
5 indicate that COAT" -- which stands for chronic  
6 opioid analgesic therapy -- "exposure will lead to  
7 abuse/addiction in a very small percentage of  
8 patients. This percentage can be dramatically  
9 decreased by preselecting CPP" -- so, let me look  
10 and see what the "CPP" is. That's "chronic pain  
11 patients" -- "for no previous or current history of  
12 drug/alcohol abuse/addiction [sic]."

13 Q I'll hand you what I've marked as Vorsanger  
14 Exhibit 21.

15 (Long-term opioid management for  
16 chronic noncancer pain (Review)  
17 was marked as Vorsanger 21 for  
18 identification, as of this  
19 date.)

20 Q Can you identify Exhibit 21?

21 A Yes. This is the Cochrane review that I  
22 had referenced earlier, and it's entitled "Long-term  
23 opioid management for chronic noncancer pain," a  
24 "(Review)." And the last author on it is Roger  
25 Chou, C-H-O-U.

1 Q And what is the -- it says on the front  
2 "Cochrane Library."

3 What's the Cochrane Library?

4 A So, the Cochrane Library is a database of  
5 systemic reviews. And the people who do these  
6 reviews look at a wide variety of studies, they  
7 identify the level of evidence in each of these  
8 studies and what the quality might be, pardon me,  
9 and then do a conclusion based on those data.

10 Q And what's the conclusion of this review  
11 relating to addiction?

12 A So, I'm going to read that from the article  
13 itself.

14 The article -- the authors have a  
15 conclusion, but I like the conclusion that they also  
16 have in plain language. It's a "Plain Language  
17 Summary." And what that says: "The findings of  
18 this systemic review suggest that proper management  
19 of a type of strong painkiller (opioids) in  
20 well-selected patients with no history of substance  
21 abuse -- addiction or abuse can lead to long-term  
22 pain relief for some patients with a very small  
23 (although not zero) risk of developing addiction,  
24 abuse, or other serious side effects. However, the  
25 evidence supporting these conclusions is weak" --

1 so, they talk about the level of evidence that they  
2 have -- "and long-term studies are needed to  
3 identify the patients who are most likely to benefit  
4 from treatment."

5 Q Let's switch gears and talk about Nucynta.  
6 What were your responsibilities for  
7 Nucynta?

8 A So, I was a senior medical director when  
9 Nucynta was approved, working at the U.S. medical  
10 affairs group at Janssen. And my responsibilities  
11 were similar to what I've already described. I was  
12 responsible for the design of clinical studies, if  
13 we had decided that we wanted to have studies; to  
14 review data that had come in from the studies that  
15 were done by our research and development group.

16 I published a number of post hoc analysis  
17 from the data that were done by R&D group. I  
18 continued to work with our outcomes research group.  
19 I continued to work with our pharmacovigilance  
20 group. I continued to do some work -- do work on  
21 the promotional review committee, as I had  
22 mentioned. And then continued to run the active  
23 surveillance program, amongst other activities, as  
24 well.

25 Q What is Nucynta?



1 A Nucynta is an opioid analgesic.

2 Q And is it different from other opioid  
3 analgesics?

4 A Yes. An analgesic is a pain medication.

5 Nucynta is different from other pain  
6 medications. It's a semisynthetic opioid pain  
7 medication. Although its exact mechanism of action  
8 is unknown, the preclinical studies suggest that it  
9 has two mechanisms of action: One is a typical  
10 opioid-type effect, and the second one is a  
11 norepinephrine reuptake inhibitory effect. And it's  
12 believed that both of those mechanisms provide pain  
13 control.

14 Q And what's the significance of having two  
15 mechanisms of action?

16 A Well, the opioid effect from Nucynta is  
17 weaker from -- than some of the other strong  
18 opioids, such as oxycodone or morphine.

19 But by having the two mechanisms -- and in  
20 clinical studies, we were able to show that the  
21 product delivered very effective -- was both -- the  
22 efficacy was similar to oxycodone, although the  
23 studies weren't powered specifically to look at  
24 that, but we certainly saw that in our studies, and  
25 had -- was quite effective.

1 Q What about with regard to adverse event  
2 profile?

3 A So, because the effect that the opioid  
4 receptor is -- was postulated or hypothesized, and  
5 certainly thought to be -- from other studies, to be  
6 weaker than a strong opioid, we thought that it  
7 might be likely that there may be less abuse  
8 associated with tapentadol compared to some of the  
9 stronger opioids, such as oxycodone or morphine.

10 Q How about other adverse events?

11 A So, in addition to that, we saw -- because,  
12 again, less of an effect on the opioid receptor  
13 relative to the other ones, we saw some potential GI  
14 benefits, as well, which, which -- the reason was  
15 that we talked about.

16 Q And what's the approved indication for  
17 Nucynta immediate-release version?

18 A So, Nucynta immediate-release is approved  
19 for the treatment of acute pain. What we're -- and  
20 I'm paraphrasing it now -- for moderate to severe  
21 acute pain in patients requiring opioid analgesics,  
22 where medications of -- that were -- and I'm just  
23 describing what's in the package insert -- where  
24 lesser medications would be inadequate to provide  
25 pain control to those patients.

1 Q And for the exact wording of that, we would  
2 go to the FDA package insert for Nucynta --

3 A Yes. So --

4 Q -- similar to the one that we looked at for  
5 Duragesic?

6 A -- we could do that and read the exact  
7 indication for that and for ER. But I do not -- I  
8 don't have them memorized at this point.

9 Q What is the approved, so far as you  
10 remember, the approved indication for the  
11 extended-release Nucynta?

12 A So, the approved indication for extended  
13 release is for pain -- as I recall it, is -- and  
14 again, you -- one can go to the package label for  
15 the exact wording -- for pain severe enough to  
16 require an opioid analgesic around the clock for an  
17 extended period of time, where the pain cannot be  
18 treated by lesser methods.

19 Q And which conditions was Nucynta ER  
20 indicated for?

21 A So, Nucynta ER is indicated for chronic  
22 pain regardless of ideology.

23 Q And anything else?

24 A It has another indication for neuropathic  
25 pain.

1 Q What is neuropathic pain?

2 A So, neuropathic pain is pain associated  
3 with nerve. It can be nerve injury. This is  
4 important because for people who have neuropathic  
5 pain, some patients describe opioids as being not  
6 very effective to treat the neuropathic pain.

7 So, the fact that we were able to  
8 demonstrate that tapentadol is effective in the  
9 treatment of neuropathic pain -- and we had good  
10 clinical data to support that -- placebo-controlled  
11 trials enabled us to promote it and also to be in a  
12 position for physicians to understand that there is  
13 an opioid analgesic that may be helpful in treating  
14 their patients with neuropathic pain.

15 Q Were there any aspects of Nucynta that made  
16 the product less attractive for abusers?

17 A So, the immediate release formulation, it  
18 may be less attractive to abusers, because we talked  
19 about the, the dual mechanism and some of those  
20 reasons.

21 For the extended-release formulation, it  
22 was the same drug, tapentadol, but the company  
23 realized that if we were introducing an  
24 extended-release opioid into the marketplace with  
25 what was being discussed about opioid abuse, that we

1 thought it would be important to put a coating on  
2 that had abuse-deterrent qualities.

3 We didn't have labeling for it, but we had  
4 lab studies that were done by our colleagues at  
5 Gruenthal to show that the product was very  
6 difficult to -- the -- that formulation was  
7 difficult to defeat using the typical type of  
8 methods that people who would abuse or are addicted  
9 to these products would use to try to break in to  
10 get to the tapentadol.

11 Q That was going to be my next question.

12 Did you undertake testing to determine the  
13 effectiveness of the protective coating?

14 A We did in the laboratory tests, yes.

15 Q And what kinds of tests were those?

16 A Those were tests where the tablets were  
17 hammered or exposed to common solvents or other ways  
18 that addicts might typically try and break in. And  
19 the coating was resistant to those types of  
20 methodologies.

21 Q And was that data made public?

22 A It was. A number of articles were  
23 published, and I co-authored some of those.

24 (Evaluation of the  
25 tamper-resistant properties of

1 tapentadol extended-release  
2 tablets: Results of in vitro  
3 laboratory analyses was marked  
4 as Vorsanger 22 for  
5 identification, as of this  
6 date.)

7 Q I've handed you what I've marked as  
8 Vorsanger Exhibit 22.

9 Can you identify that document?

10 A Yes. So, this is one of the articles that  
11 I just referenced. It's entitled "Evaluation of the  
12 tamper-resistant properties of tapentadol  
13 extended-release tablets: Results of in vitro  
14 laboratory analyses."

15 Q And what were the conclusions of that  
16 article?

17 A So, the conclusions of the article were as  
18 follows, and I'll read the conclusion verbatim.

19 "In vitro results from tampering attempts  
20 presented herein demonstrate that tapentadol ER  
21 tablets were resistant to those forms of physical  
22 manipulation. Tapentadol ER tablets were also  
23 generally resistant to dissolution in most solvents.  
24 Developing tamper-resistant formulations is an  
25 important step in strategies to mitigate opioid

1 abuse."

2 Q Did the labeling for the extended-release  
3 Nucynta include a claim that the product was  
4 abuse-deterrent?

5 A No, it did not.

6 Q Why not?

7 A FDA had developed specific guidelines on  
8 the types of studies that would need to be done to  
9 have language in the package insert to make those  
10 claims, and those -- all of those studies that would  
11 need to be done to be able to have that language  
12 were not done; and, therefore, that language was not  
13 put into the package insert.

14 Q Did you have data on whether -- or that  
15 spoke to the question of whether Nucynta, in either  
16 formulation, was less attractive to abusers?

17 A Yes, we did.

18 Q What kind of data?

19 A So, I had undertaken a study with a number  
20 of authors. I believe they were, some of them  
21 were -- or many of them were, were scientists  
22 working as a RADARS advisory board. And I believe  
23 Dr. Hilary Surratt was probably the first author.  
24 And we looked, in part, on the street price of the  
25 medications. What would the street price be to

1     addicts who -- to evaluate the various opioid  
2     medications? That was a study that was done.

3             The street price was, I believe -- and I  
4     don't have the article in front of me -- highest for  
5     a drug like OxyContin and lowest for a drug like  
6     tapentadol.

7             Q     If you thought the product was going to be  
8     less attractive to abusers, why did the company  
9     bother with a tamper-resistant formulation?

10            A     The company realized that, in the United  
11     States, if we were going to bring an  
12     extended-release formulation into the U.S. market,  
13     that the responsible thing to do would be to have  
14     some type of abuse-deterrent methodology, even  
15     though we knew, from the IR formulation of  
16     tapentadol, which was brought to market two years  
17     earlier, that this was not a substance that was --  
18     appeared to be very desirable to people who wanted  
19     to abuse the product, from all of the methodology  
20     that I had already gone over today.

21            But still, in all, we felt it was the right  
22     thing to do; so, we introduced this protective  
23     covering.

24            Q     What did the company do to encourage safe  
25     and effective use of Nucynta and Nucynta ER?



1           A       So, to encourage safe and effective use of  
2       the product, it was done through a number of ways.

3                   We worked closely with regulatory agencies  
4       to ensure that our product labeling was up to date,  
5       had the most accurate information about our  
6       products; we also had educational courses; and there  
7       was a Nucynta REMS, as well.

8           Q       Can you explain what a REMS is?

9           A       Yes. So, "REMS" stands for "Risk  
10      Evaluation and Mitigation Strategy." The REMS was  
11      put together, and I believe REMS were required for  
12      all of the extended-release opioids.

13                   And REMS really was a convenient tool for  
14      prescribers or clinicians to capture important  
15      information about the product for its safe and  
16      effective use. It was an excellent educational tool  
17      and contained a lot of information.

18                   My opinion also is that it was handy and  
19      easy to use. There was a lot of important  
20      information that you could use. There was a quiz  
21      that you could take to see how well you understood  
22      it, and we -- the company collected -- this was all  
23      voluntary; they didn't have to do the quiz, if they  
24      didn't want to -- if they wanted to send it to the  
25      company, it would give us an idea of how well people

1 understood the information in there.

2 (JAN-MS-01489228 through 275 was  
3 marked as Vorsanger 23 for  
4 identification, as of this  
5 date.)

6 Q I've handed you what I marked as Vorsanger  
7 Exhibit 23.

8 Can you identify that document?

9 A Yes. This is the REMS for tapentadol.

10 Q And you're familiar with this from your  
11 time at Janssen?

12 A Yes.

13 Q And when you say it's the REMS, there -- in  
14 section II, it describes REMS elements.

15 Can you explain what those are?

16 A Yes. So, the REMS elements are how the  
17 medication guide -- and that talks a little bit  
18 about what we need to know. And then there is a  
19 thing called ETASU, an "Elements to Assure Safe  
20 Use."

21 So, the medication guide is something that  
22 can be shared with patients, how to use the  
23 medication. And it says that -- to keep the  
24 extended release away, safe away from children.  
25 Accidental use by a child, even in a medical

1 emergency can result in death, and talks about that.

2 And this -- and this directions are read  
3 the med guide that comes with Nucynta ER before you  
4 start taking it. So, we're telling patients that  
5 this is important information that they need to have  
6 and they need to read before they start taking the  
7 medication.

8 Q Does the REMS also include training  
9 materials for physicians?

10 A That's right. So, there are -- there's  
11 materials in here, it says, under "Elements to  
12 Assure Safe Use," the ETASU, "Healthcare  
13 professionals who prescribe...will receive  
14 training." That information is in the REMS.

15 And we -- Janssen "will ensure that the  
16 training will be provided to healthcare  
17 professionals who prescribe Nucynta ER." And, "To  
18 become trained, each prescriber will be provided  
19 with the ER educational materials," which were  
20 included in the REMS.

21 And then the training material, I think, is  
22 important for proper patient selection, appropriate  
23 dosing.

24 "General principles of safe opioid use,"  
25 and information -- including "information about

1 opioid abuse and how to identify patients who are at  
2 risk for addiction."

3 "Potential abuse, misuse, overdose, and  
4 addiction from exposure to opioids" is discussed and  
5 the risks are gone over, as well.

6 So -- and it goes on and on, in quite a --  
7 it's quite a lot of information, I think, included  
8 in the document.

9 Q Let's take a look at Exhibit -- I think  
10 it's Appendix 3, page -- it's page 21 of the  
11 document.

12 A Okay. Appendix 3.

13 Q What is Appendix 3?

14 A "Prescribing Nucynta ER Healthcare  
15 Professional Educational Program: A Guide for  
16 Healthcare Professionals Who Intend to Prescribe  
17 Nucynta ER."

18 Q And is that the physician educational  
19 material that you were just describing?

20 A That's correct, yes.

21 Q And can you turn to page 29 of that -- or  
22 I'm sorry, 28.

23 A Yes.

24 Q Does that have any discussion of the risk  
25 of addiction?

1           A     Yes.  So, "Nucynta ER Risks, Abuse, Misuse,  
2     and Addiction," in the document, as you indicated,  
3     on page 28 talks a little bit about the risk of  
4     addiction.

5                     Do you want me to read this or just  
6     identify --

7           Q     No.  My only question is whether addiction  
8     is covered in the educational materials.

9           A     Yes.  Yes, it is.

10          Q     How are these materials disseminated?

11          A     So, these were disseminated free of charge  
12     to people who were prescribers of the medication,  
13     and then they could go through it.  And as I  
14     mentioned, if they wanted to, there was an optional  
15     quiz they could take.

16          Q     Did they go out via your healthcare  
17     professional letter?

18          A     Yes, I believe that they did.

19          Q     What else did Janssen do to ensure safe and  
20     effective use of Nucynta?

21          A     Well, we continued to monitor the product,  
22     to ensure that we understood about its -- the abuse  
23     that was going on.  We talked about that, as well.

24          Q     Well, you described the safety surveillance  
25     program for Duragesic.

1 A Correct.

2 Q Was the one for Nucynta similar?

3 A The same program. The same, the same type  
4 of elements that we used for Duragesic were used for  
5 Nucynta, as well.

6 Q So, that would include SCEPTRE?

7 A So, that would include passive surveillance  
8 using SCEPTRE and FDA AERS that we talked about, the  
9 databases that were appropriate. We also had RADARS  
10 data, that we've talked about.

11 And with Nucynta, we brought on an  
12 additional methodology that we didn't have for  
13 RADARS; we also brought on our work from Inflexxion.  
14 And the Inflexxion data were important with this  
15 because it provided additional information for us.

16 So, Inflexxion had one network, which  
17 looked at individuals coming in for treatment for  
18 substance abuse.

19 But another program that Inflexxion had,  
20 which I was interested in, was a thing called teen  
21 CHAT. So, now we were able to identify and  
22 understand how opioid analgesics might be abused in  
23 an age group that -- a younger age group, teenagers.  
24 So, that was an important, I believe, an important  
25 addition to provide more information so we could

1 really understand even more about the abuse of our  
2 products.

3 (JAN-MS-00228548 was marked as  
4 Vorsanger 24 for identification,  
5 as of this date.)

6 Q So, I'm going to hand you a document that  
7 I've marked as Vorsanger Exhibit 24.

8 Can you identify this document?

9 A Yes. This document is entitled "Nucynta,"  
10 and in parentheses, "(Tapentadol) Extended-Release:  
11 The Fourth Safety Surveillance Plan Progress  
12 Report."

13 Q And this would be -- what kind of report is  
14 this?

15 A Well, this is a safety report that would  
16 contain information from our pharmacovigilance  
17 group, as well as information from -- and we talked  
18 about the passive surveillance and the work that  
19 they do, as well as the active surveillance  
20 materials that I've been talking about.

21 Q So, these are combined periodically in  
22 progress reports?

23 A Yes, that's correct. So, this information  
24 was presented to FDA at regular intervals, as  
25 requested by FDA, when they wanted to see this

1 material. And it captured a lot of -- extensively,  
2 the information that we have and had as a company  
3 about all of the methodology and all of that work.

4 Q If you turn to the table of contents,  
5 page 9.

6 A Uh-huh.

7 Q There is a reference to "NAVIPPRO systems  
8 programs"?

9 A Yes.

10 Q What is that?

11 A So, NAVIPPRO is the work from Inflexxion  
12 that I just spoke about. That was their system for  
13 monitoring for abuse. And it had multiple elements,  
14 some of which I've touched on.

15 The AS --

16 Q And --

17 A Sorry.

18 Q -- you described the teen chat program;  
19 that's what's referred to here as --

20 A Yes.

21 Q -- "CHAT."

22 A Yes.

23 Q And what were the other elements?

24 A So, the ASI-MV, as -- my recollection was,  
25 this was a computerized version of the ASI-MV for



1 individuals coming in to treat for substance abuse.

2           Inflexxion took over the web monitoring  
3 from Pinney. So, we continued to monitor for  
4 Internet mentions of abuse of our products, I think  
5 going way back from the work that we started with  
6 Duragesic and continued, but this was a different  
7 company that took it over.

8           Q     And if you could turn to page 81 of the  
9 report. And if you look at the first full -- I  
10 guess the last part of the carryover paragraph on  
11 page 81, does that describe the objectives of the  
12 NAVIPPRO program?

13           A     Yes. It talks about the objectives for the  
14 ASI-MV and talks a little -- talks more about some  
15 of the methodology involved in the ASI-MV, and how  
16 it collects data, et cetera. And there are some  
17 tables in here, as well, talking about it.

18                     There's geographical -- it looks like there  
19 is something on geographical distribution.

20                     And it talks about various opioid  
21 analgesics in table 14.

22           Q     And can you just read that last sentence of  
23 the carryover paragraph on 81?

24           A     Yes.

25                     "The ASI-MV assessment gathers

1 self-reported data in near real time on respondents  
2 from a network of facilities across the United  
3 States. These facilities utilize the assessment for  
4 treatment planning and triage in relation to  
5 substance abuse problems."

6 Q And how about in the prior section there,  
7 on the top of 81, the last sentence, again, of the  
8 carryover product [sic]?

9 A In this report?

10 Q No. Before that.

11 A Oh.

12 Q The last sentence there.

13 A The last sentence, sure.

14 "The various data sources are intended to  
15 complement each other; an indication of increased  
16 abuse of a particular product found in one data  
17 source can be examined and evaluated with other  
18 sources within NAVIPPRO. Continuous examination of  
19 these data streams allows monitoring of trends over  
20 time for drug abuse at a product-specific level."

21 Q And what did the surveillance show, again,  
22 over the years that the company looked at it, for  
23 the Nucynta products?

24 A For the Nucynta products, the data from the  
25 NAVIPPRO system was very similar in conclusion to

1 what I had also reported for the work that came out  
2 of RADARS.

3 And both systems, together, identified, in  
4 general, low mentions of abuse of Nucynta.

5 Q Now, counsel showed you a -- an exhibit --  
6 I think it was marked as Exhibit 10. Do you still  
7 have that?

8 A Let's see. What number, I'm sorry?

9 Q Ten.

10 A Okay.

11 (Exhibit 10 was shown to the  
12 witness.)

13 Q Could you explain what that data is?

14 A So, these are data that were generated for  
15 SCEPTRE. These look like raw data to me. These are  
16 data that describe reports of Nucynta with the  
17 reaction of drug abuse. These may be -- this is  
18 information that would come into the company. Some  
19 of it may have come in from RADARS; it may have come  
20 in from other sources, as well. And these data  
21 would be analyzed, duplications would be removed.  
22 And then, for the information, where we had  
23 information, we would generate reports. And those  
24 reports would be put as part of a safety -- put  
25 information as part of a submission for a safety

1 report to the FDA.

2 Q So, after the data were analyzed, would an  
3 assessment be made as to whether there was a safety  
4 signal that the data were suggesting?

5 A Yes. So, as part of the activities, of not  
6 only processing, as to -- it would be ongoing,  
7 looking at it to see whether there was any  
8 suggestion that there was a safety signal. And if  
9 so, we were to determine what that would be. And  
10 then if, if there was a need be, we would act on  
11 that signal.

12 Q And that would be reflected in the analysis  
13 that's presented in the reports of the analysis of  
14 the SCEPTRE data?

15 A Yes. And that would be information that  
16 would be shared, yes, through -- in the  
17 pharmacovigilance group and then, as I already  
18 mentioned, with FDA.

19 Q And do you recall whether there were safety  
20 signals with regard to Nucynta or Nucynta ER that  
21 suggested a higher rate of abuse?

22 A No, I do not.

23 Q I also want to show you an exhibit that  
24 counsel marked as Exhibit 3.

25 (Exhibit 3 was shown to the

1 witness.)

2 A Okay.

3 Q This is a series of emails between you and  
4 Rick Dart.

5 Do you remember that discussion earlier  
6 this morning?

7 A Yes, I do.

8 Q And Dr. Dart was with RADARS?

9 A That's correct, yes.

10 Q And you had sent Dr. Dart some emails  
11 concerning a paper that RADARS was preparing with  
12 some other authors?

13 A Yes, that's right.

14 Q And you read a number of these emails into  
15 the record at the request of the State's counsel.

16 But he didn't ask you to read the -- your  
17 reply to Dr. Dart in response to his email asking if  
18 you wanted to comment on the paper.

19 Can you just read that reply into the  
20 record? That's the second email down in the chain.

21 A Yes, I can.

22 This is, as you already indicated, an email  
23 from me to Dr. Dart. The subject is "Generic Drugs  
24 Paper," and the date is May the 9th of 2007.

25 And what I wrote to Rick Dart was the

1 following:

2 "Rick,

3 "Thanks for asking. The company's position  
4 is one in which we prefer to be 'hands off.' The  
5 intent is to ensure the unimpeded flow of academic  
6 information by industry. What we would ask is that  
7 we have a review only to ensure fair balance of our  
8 product but not" -- and I underline "not" -- "to  
9 provide input into the science or strategic  
10 description of the manuscript."

11 And I signed it.

12 Q And what did you mean by that?

13 A It was our position that the data were  
14 generated by RADARS. They had the best  
15 understanding of what the data meant. We wanted the  
16 conclusions from the data to be RADARS' conclusions  
17 and not Janssen's conclusions, and that they would  
18 come up with that independently.

19 But we wanted to make sure that whatever is  
20 written about the product -- let's say it's  
21 mechanism of action -- or if there were any clinical  
22 information or other things that the RADARS office  
23 decided that they wanted to include, that we would  
24 have an opportunity to review just to ensure that  
25 that information was presented fairly and in fair

1 balance.

2 MR. LIFLAND: No further questions.

3 MR. DUCK: Okay. Let's take a break,  
4 because I think Amanda needs a little break,  
5 and then we'll come back in 5 minutes. How  
6 about that? And I'll ask you some more  
7 questions.

8 THE WITNESS: Okay.

9 THE VIDEOGRAPHER: Off, 4:22.

10 (Recess taken.)

11 THE VIDEOGRAPHER: We're back at 4:33.

12 FURTHER EXAMINATION BY

13 MR. DUCK:

14 Q All right. You understand you're still  
15 under oath?

16 A Yes, sir.

17 Q Okay. Has Janssen asked you to be an  
18 expert witness in this case?

19 A Not specific -- not directly.

20 Q Have they asked you indirectly?

21 A They had -- we were discussing whether I  
22 might be a representative, but this is something  
23 that I -- I had other things that I was doing, and I  
24 was not able to fulfill that role.

25 Q Are you intending to serve as an expert

1 witness in this case in the future?

2 A I don't know. At the moment, I don't know.

3 Q Are you being paid to be here today?

4 A No, I'm not.

5 Q Since you retired from Janssen or Johnson &  
6 Johnson, have you worked or consulted on any  
7 litigation for those companies?

8 A No. I provided testimony for another --  
9 for the MDL litigation, and that's it.

10 Q The MDL opioid litigation?

11 A That's right.

12 Q Has Janssen or Johnson & Johnson asked you  
13 to testify at the trial of this Oklahoma case?

14 A No, they have not.

15 Q If they do, would you be willing to come to  
16 Oklahoma to testify at Janssen's request?

17 MR. LIFLAND: Object to the form of the  
18 question.

19 A I'd have to think about that, because I've  
20 been a witness of fact, and that was sort of where I  
21 was. So, I don't -- I haven't thought about  
22 anything beyond that.

23 Q Are you able to travel?

24 A I'm able to travel, depending on what else  
25 might be going on in my life. But, yes, I'm able to



1 get on a plane if I have to.

2 Q Okay. You're physically able to?

3 A Yes, I am.

4 Q All right. Are you going to be out of the  
5 country or otherwise indisposed for the months of  
6 June, July, or August?

7 A I don't know.

8 Q Currently, you don't have plans to be  
9 indisposed for those entire three months?

10 A Not that I know of.

11 Q You know that heroin was originally  
12 manufactured by Bayer in Germany?

13 A I had heard something, but I -- it's not a  
14 fact that I have at my fingertips.

15 Q You didn't know heroin was first used as a  
16 medicine?

17 A I, I believe so, but I, I -- again, it's  
18 something I don't have as a direct fact, but it  
19 sounds like something I might have heard.

20 Q Did you know that heroin was marketed as  
21 nonaddictive?

22 A No, I did not know that.

23 Q And that would be wrong, because heroin is  
24 addictive, right?

25 MR. LIFLAND: Object to the form of the

1 question.

2 A When it was marketed at the time, it may or  
3 may not have -- they may or may not have known it  
4 was addictive. But we know subsequently it is  
5 addictive.

6 Q Yes, it is.

7 When Duragesic first hit the market,  
8 Janssen did not market it for noncancer pain; isn't  
9 that right?

10 A Again, that happened before I was at the  
11 company, in the period of 1990 to 2005.

12 That may be my hearing aid that you're --

13 Q Oh, I'm sorry.

14 A Yeah, that's fine.

15 And so, it's my understanding it was used  
16 for noncancer-related pain -- for cancer-related  
17 pain. I'm sorry.

18 Q You're aware that, during the '90s, Janssen  
19 was originally apprehensive to promote Duragesic for  
20 use in noncancer pain?

21 A So, I --

22 MR. LIFLAND: Object to the form of the  
23 question.

24 A I believe that question was asked earlier  
25 of me, and I believe my response at the time was: I

1 did not have information that I could confirm that  
2 statement.

3 Q You're saying that's something I asked you  
4 earlier?

5 A Yes, you did. I believe you did.

6 Q And you don't know, one way or another?

7 A Correct.

8 Q You talked about the abuse-deterrent  
9 formulation for Nucynta when your lawyer asked you  
10 questions.

11 Do you remember that?

12 A For ER, Nucynta ER, the abuse-deterrent for  
13 Nucynta ER.

14 Q Sure.

15 A Yes.

16 Q You said that wasn't in the package insert,  
17 right?

18 A So, what I had testified was that there is  
19 no labeling in the package insert for language  
20 around abuse deterrence for that formulation,  
21 correct.

22 Q Right.

23 A Yes.

24 Q Did Janssen get the FDA's approval to  
25 actually make Nucynta ER abuse-deterrent?

1           A     I don't remember what discussions went back  
2     and forth on it. But the -- in order to have that  
3     type -- and I want to make sure I'm answering your  
4     question; so, if not, please tell me -- in order to  
5     get that type of labeling, there were a series of --  
6     there were a series of studies that would needed to  
7     have been done.

8                     And I don't know if that answers your  
9     question or not.

10          Q     Yeah, I'm not worried about the labeling.

11          A     Okay.

12          Q     I understand your testimony there.

13                     My question is: Before Janssen actually  
14     made the tablets abuse-deterrent, physically --

15          A     Yes.

16          Q     -- did Janssen obtain FDA approval to do  
17     that?

18          A     So, the original -- the studies were  
19     actually done without the abuse-deterrent  
20     formulation. The abuse-deterrent formulation was  
21     then introduced, and I believe bioequivalence  
22     studies needed to be done to show that the drugs  
23     with the abuse-deterrent formulation were  
24     bioequivalent to the nonabuse-deterrent formulation  
25     tablets, so that we could use that. So -- but I

1 don't know what discussions Janssen and FDA had  
2 around that.

3 So, the drug could be -- could have been  
4 approved without the abuse-deterrent formulations,  
5 based on the clinical data, but they had done  
6 bioequivalence studies.

7 Q So, you don't know, one way or another,  
8 whether the FDA approved the abuse-deterrent  
9 formulation in Nucynta ER, as opposed to the  
10 nonabuse-deterrent formulation?

11 A So, I don't know the -- and I'm trying --  
12 so, the answer is no. I want to give you a simple  
13 answer on that. But I wanted to give you an  
14 accurate answer was -- how the studies were done --

15 Q Is Janssen --

16 A -- which I did.

17 Q Thank you.

18 Is Janssen required to obtain FDA approval  
19 to make its products safer?

20 A I'm not sure I understand what that  
21 question is.

22 Q What don't you understand?

23 A In what way would they be required to do  
24 that? What do you mean by that?

25 Q I don't know. I'm asking you.

1           A     So, if a product was going to be developed  
2     with certain attributes, then discussions would need  
3     to go on between a company, Janssen, and FDA for  
4     what the attributes of the product would be. So, if  
5     the company felt that this was something that would  
6     be safer, in order to be able to make a label claim  
7     that it would be safer, the studies would need to be  
8     done, and those studies are studies that would need  
9     to be done in discussion with FDA.

10          Q     I know this might be difficult, because  
11     you've done this for so long, but let -- I'm not  
12     asking about label changes right now. I'm just  
13     asking about reformulation, which is what happened  
14     with Nucynta ER, right? No label change, but it did  
15     have an abuse-deterrent formulation, right?

16          A     It -- and I apologize, Counselor. So, it  
17     had a formulation that had abuse-deterrent  
18     qualities, but we didn't market it that way.

19          Q     Okay. Great. We're on the same page.

20          A     Okay.

21          Q     That's what I'm talking about.

22          A     Right.

23          Q     It would have been okay for Janssen to sell  
24     Nucynta ER without the abuse-deterrent --

25          A     Yes.

1 Q -- qualities?

2 A That's correct.

3 Q Right?

4 A Yes.

5 Q But Janssen sold it with the  
6 abuse-deterrent qualities, even though that wasn't  
7 in the label?

8 A Yes.

9 Q Janssen, in your view, went beyond what it  
10 had to do?

11 A Yes.

12 Q And my question is: Did Janssen have to  
13 obtain FDA approval to do that?

14 A Yes, to put the formulation on there, they  
15 would have had to have some kind of discussion with  
16 FDA about it.

17 Q Thank you.

18 A Okay. Sorry it took so long to get.

19 Q That's okay.

20 You said "some discussion."

21 Do you mean the FDA formally approved?

22 A Yes. They would have to have dialogue with  
23 the FDA about what was intended, what would be done,  
24 et cetera.

25 Q What did you do to prepare for this

1 deposition?

2 A I met with my attorneys, these gentlemen.

3 Q And they are your attorneys, right?

4 A They are both the company and mine, yes.

5 Q Are you paying them for their time?

6 A No, sir, I'm not.

7 Q How many times did you meet with them?

8 A We met several times.

9 Q How many times?

10 A Two -- we met three times.

11 Q Before today?

12 A Yes.

13 Q Okay. When was that?

14 A Earlier in the week, several times, three  
15 times.

16 Q This week?

17 A Yes.

18 Q For how many hours each time?

19 A I don't recall exactly. There were periods  
20 of time during two days and a short session the  
21 third day.

22 Q And that was for preparation for this  
23 deposition?

24 A Yes, that's correct.

25 Q I've asked you questions about what you



1 learned and what you knew from your time working at  
2 Janssen, right?

3 A I'm sorry, say it again?

4 Q I've asked you questions about what you  
5 knew and what you learned from working at Janssen --

6 A Yes.

7 Q -- correct?

8 A You did.

9 Q What did you need to be prepped about for  
10 this deposition?

11 MR. LIFLAND: Object to the form of the  
12 question.

13 A Well, some of it would be to review some  
14 information that I may not have seen for a while.

15 Q What information?

16 A Some of the --

17 MR. LIFLAND: Object to the form of the  
18 question.

19 A Some of the information from some of the  
20 articles, to review again what we talked about,  
21 iatrogenic addiction. So, the articles that I  
22 looked at were -- that I -- that was discussed were  
23 articles that I hadn't seen.

24 Q Why does that require lawyers?

25 MR. LIFLAND: Object to the form of the

1 question.

2 A It was information that I was interested in  
3 and that went over -- and they were -- provided that  
4 information to me.

5 Q How many documents did you review in  
6 preparation for this deposition?

7 A I don't recall.

8 Q Approximately?

9 A I don't know. There was some emails and  
10 some other documents. I don't recall.

11 Q More than 10?

12 A No, I don't think so.

13 Q Less than 10?

14 A I -- again, I don't recall. So, now I'm  
15 being asked to say, well, okay, being -- given that  
16 I don't recall, yeah, I would say less than --  
17 that's probably right.

18 Q It was this week.

19 A Yes.

20 Q I mean, it's not that hard to remember what  
21 happened this week, is it, sir?

22 A No. But if I -- I'm someone who tends to  
23 answer in a precise manner. So, if I can't give you  
24 a precise answer, I would, I would qualify that,  
25 which I did.

1 But it would be probably less than 10, 10  
2 or less.

3 Q Okay. Because that happened this week, you  
4 had trouble remembering, and I've asked you  
5 questions about the last 19 years.

6 A Yes, sir.

7 Q Have you had trouble remembering things --

8 A No, sir, I don't.

9 MR. LIFLAND: Object to the form of the  
10 question.

11 Q Okay.

12 A I just wanted to be accurate in terms of  
13 what I had, in giving the information I provide.

14 Q Who did you talk to in preparation for this  
15 deposition, other than your attorneys?

16 A No one.

17 Q You didn't talk to anybody at Janssen?

18 A I had one, I had one conversation with  
19 Bruce Moskovitz.

20 Q Okay. What did y'all talk about?

21 A Bruce wanted, just, me to review the  
22 information around the active surveillance, the  
23 active surveillance methodologies.

24 Q Okay. What specifically did he tell you?

25 A He was just -- I worked with Bruce, and I

1 had developed it. So, he had some questions about  
2 what were some of the programs that were in place  
3 before RADARS. So, we talked briefly about that.

4 Q Have you covered all of those issues today?

5 A Yes, we did.

6 Q Why did Bruce Moskowitz reach out to you?  
7 For his deposition or for your deposition?

8 A For -- he had some questions on what he  
9 wanted to know, and he wanted to make -- and since I  
10 had developed these programs and I worked on them,  
11 he reached out to me to make sure that his  
12 information was correct.

13 Q Because he was being deposed?

14 A Yes.

15 Q All right. Did y'all talk about your  
16 deposition today, you and Bruce?

17 A No.

18 Q Did you talk to anybody else at Janssen?

19 A No.

20 Q Did you talk to anybody else, other than a  
21 person at Janssen or other than your lawyer -- just  
22 anybody -- about this deposition?

23 A I did not.

24 MR. DUCK: Pass the witness.

25 MR. LIFLAND: No questions.

January 17, 2019

317

1 MR. FIORE: Nothing from Teva.

2 MS. NEWSOME: No questions.

3 MR. DUCK: Thank you for your time, sir.

4 THE WITNESS: Thank you.

5 MR. DUCK: We're all done.

6 THE VIDEOGRAPHER: Off, 4:46.

7 (Time adjourned: 4:46 p.m.)

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January 17, 2019

318

## C E R T I F I C A T E

I, AMANDA McCREDO, a Shorthand Reporter  
and Notary Public of the State of New Jersey,  
do hereby certify:

That the witness whose examination is  
hereinbefore set forth, was duly sworn, and  
that such examination is a true record of the  
testimony given by such witness.

I further certify that I am not related to any  
of the parties to this action by blood or  
marriage; and that I am in no way interested in  
the outcome of this matter.



AMANDA McCREDO

January 17, 2019

319

## ERRATA SHEET FOR THE TRANSCRIPT OF:

Case Name: State of Oklahoma v. Purdue Pharma,  
et al.

Dep. Date: January 17, 2019

Deponent: Gary Vorsanger, M.D., Ph.D.

## CORRECTIONS:

Pg.	Ln.	Now Reads	Should Read	Reason
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\_\_\_\_\_  
Signature of Deponent

SUBSCRIBED AND SWORN BEFORE ME

THIS \_\_\_\_ DAY OF \_\_\_\_\_, 20\_\_

\_\_\_\_\_

(Notary Public) MY COMMISSION EXPIRES: \_\_\_\_\_

January 17, 2019

320

## ACKNOWLEDGMENT OF DEPONENT

I, \_\_\_\_\_, do hereby  
certify that I have read the foregoing  
pages, and that the same is a correct  
transcription of the answers given by me  
to the questions therein propounded,  
except for the corrections or changes in  
form or substance, if any, noted in the  
attached Errata Sheet.

\_\_\_\_\_  
GARY VORSANGER, M.D., Ph.D.

Subscribed and sworn to  
before me on this \_\_\_\_\_ day  
of \_\_\_\_\_, \_\_\_\_\_.

\_\_\_\_\_  
Notary Public